Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

Roche To Shell Out $1.4 Billion To Acquire Igen; Immunoassay Competition Now Expected To Ratchet Up

Under the threat of losing its entire immunoassay business, Roche Holding (Basel, Switzerland) has agreed to pay a hefty $1.4 billion to acquire Igen International (Gaithersburg, MD). Through the acquisition, Roche will secure non-exclusive, fully paid-up, worldwide rights to commercialize Igen's Origen technology, which is the backbone of its Elecsys product line. Roche's tremendous expenditure all but guarantees that the IVD giant will now ratchet up its competitive efforts in the $6 billion worldwide immunoassay market (note: estimate includes blood banking).

Sam Wohlstadter

Meanwhile, after years of dogged perseverance in its legal battle with Roche, Igens's chairman, Sam Wohlstadter and company shareholders are now surely popping Champagne corks. Terms of the deal call for Igen shareholders to receive $47.25 per share in cash, or a total of $1.262 billion, plus one share of a new public company to be spun off by Igen that will begin with $155 million in working capital provided mostly by Roche. The new company, which will be 100% owned by Igen shareholders, will own the Origen technology and will be able to market products to the entire clinical diagnostic market, including hospital, blood bank, and reference lab markets that were previously held exclusively by Roche. ➥ *See p. 10 for more details on this historic deal.*

FDA Questions ASR Classification Of Roche's AmpliChip; Tougher Oversight Of Genetic Testing In The Works

It looks like Roche Diagnostics may have jumped the regulatory gun in its efforts to bring to market its AmpliChip CYP450 microarray (*see DTTR, August 2003, pp. 9-10*). In a July 8 letter to Roche, Steven Gutman, director of the FDA's Office of In Vitro Diagnostic Device Evaluation and Safety, questioned Roche's apparent conclusion that this microarray could be classified as an analyte specific reagent (ASR) and thus exempt from FDA premarket review requirements. The letter, which has been posted on the FDA's Web site, appears to be meant as a warning to other genetic test makers not to abuse the ASR rules. "We are actively looking for other potential offenders," Gutman tells *DTTR*. Furthermore, he says that his office is in the process of writing a notice of proposed rule making for public comment regarding tighter regulation of ASR-based genetic tests. ➥ *p.2*

▲ **AACC Plays Host To Record Crowd,** *from page 1*

Gutman says it was Roche's June 25 press release announcing the launch of its AmpliChip CYP450 microarray that caught his attention. The announcement described the AmpliChip as a microarray that "can include tens of thousands of individual DNA pieces, called probes, assembled on a thumbnail-sized glass plate, functioning like 'gene antennas.'" The press release also stated, "Roche developed the AmpliChip CYP450 microarray on the Affymetrix microarray platform" under an agreement permitting Roche to develop human diagnostic products using this proprietary instrument platform.

AmpliChip CYP450

As a result, Gutman says that the AmpliChip device does not appear to meet the FDA's definition of an ASR: a reagent "intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens." Instead, he says the AmpliChip device looks more like a "pre-built or pseudo kit" meant to run on a specific test system. In his letter, Gutman asked Heinrich Dreismann, general manager of Roche Molecular Diagnostics (Pleasanton, CA), to meet with the FDA to discuss the basis for Roche's conclusion that AmpliChip is properly classified as an ASR.

The FDA's questioning of the ASR status of the AmpliChip CYP450 microarray could throw a monkey wrench into Roche's whole strategy for the budding DNA chip market. In addition to CYP450, Roche had intended to introduce five other microarray-based assays by the end of 2004, including ASR tests for HIV-1 resistance genotyping, p53 cancer resequencing, colorectal cancer-risk prediction, cystic fibrosis, and human papillomavirus (HPV) genotyping.

This year alone, Roche announced investments totaling some $170 million in its genetic testing program, including a $70 million cash payment to Affymetrix for a license to use its DNA chip technology (*see DTTR, March 2003, p. 1*) plus a $100 million commitment to Epigenomics (Berlin, Germany, and Seattle, WA) for access to its DNA-methylation technology (*see DTTR, May 2003, pp. 3-4*).

If the FDA determines that Roche improperly classified its CYP450 microarray as an ASR, the launch of its AmpliChip line of tests could be delayed by a year or more, *DTTR* observes. But Greg Health, Ph.D., senior vice president of clinical genomics at Roche Molecular Diagnostics, tells *DTTR*, "The status of the AmpliChip product has not changed at this time. We look forward to continuing to work with the FDA to set the appropriate regulatory path for products in this new category."

Meanwhile, Gutman says his office is in the process of writing up a notice of proposed rule making that will, if promulgated, give the FDA increased oversight over ASRs being introduced for use as laboratory-developed or "home-brew" genetic tests in the clinical market. Gutman says his office is basing its proposed rules on recommendations first made by the Secretary's Advisory Committee for Genetic Testing (SACGT) back in mid-2000. This now-defunct advisory committee was chartered in 1998 to advise the U.S. Department of Health & Human Services on the adequacy of public policies for genetic testing.

Among the recommendations made by SACGT were that the FDA should be involved in the review of all new genetic tests, with the level of oversight based on

the complexity of the information generated by the test. SACGT also recommended that CLIA regulations be augmented with provisions more specific to ensuring the quality of labs conducting genetic tests. In addition, SACGT recommended that test developers be required to complete post-market studies, overseen by the CDC, demonstrating the clinical utility of their genetic tests.

In response to the argument that increased government regulation of genetic testing might prevent useful genetic tests from reaching the clinical market quickly and cheaply, Gutman told *DTTR*:

"The questions the FDA should be asking about new genetic tests are the same that labs should be asking before offering the tests, the same that consumers would want answered before having the test performed on them, and the same that anyone paying for the test would also want answered. If you establish correct thresholds, government regulation should not slow down innovation, but should assure basic responsibility and quality."

Gentris Sees Its Drug Metabolism Test On The Market In 2004

As Roche works to understand how to satisfy the FDA's regulatory concerns, a much smaller competitor—Gentris Corp. (Morrisville, NC)—may become the first IVD company to get an FDA-cleared drug metabolism test on the market. Michael Murphy, chief executive of Gentris, says his company has been in discussion with the FDA for more than six months regarding how it should proceed with filing an application for its CYP2D6 test.

Murphy says that Gentris has been performing CYP2D6 testing on an RUO basis for pharmaceutical companies since early 2001. He says the company will soon initiate a clinical study (200 to 500 patients) at a laboratory in Rhode Island to demonstrate the analytical validity of the test. Gentris aims to submit the study data to the FDA by year's end and will seek *de novo* approval from the FDA under section 513F. Pending FDA clearance, Murphy hopes to have the test on the market early next year for use in helping physicians prescribe psychiatric drugs.

In addition, Murphy says that Gentris has been working with officials at the Centers for Medicare and Medicaid Services to figure out the appropriate CPT codes for the test. He anticipates that the test will be reimbursed under several new and existing codes at approximately $250 per test.

Murphy says the Gentris 2D6 test does not require a proprietary platform and can be run using either gel-based or capillary electrophoresis methods. He says that Gentris plans to sell the test to the larger reference labs such as Quest Diagnostics, LabCorp, and Mayo Medical Laboratories and will also perform testing at its own lab in Research Triangle Park.

Regarding the regulatory speed bump that Roche's AmpliChip CYP450 microarray has encountered, Murphy would only say that, based on his discussions with the FDA, it is clear to him that any test mix designed to look at more than one DNA mutation at a time will require additional oversight from the FDA. "The FDA is sending out a clear message that it will be taking a close look at any company that makes promotional claims about their RUO or ASR reagents," he adds.

ITC Buys Diametrics' Blood Gas Test Business For $5.75M

International Technidyne Corp. (ITC—Edison, NJ), a division of Thoratec Inc. (Pleasanton, CA), has agreed to purchase the blood gas/electrolyte testing product line of Diametrics (Roseville, MN) for $5.75 million, including $550,000 of assumed debt. The acquired business consists primarily of Diametrics' IRMA SL Blood Analysis System and related reagent cartridges for point-of-care testing at hospital bedsides and operating rooms.

Larry Cohen, president of ITC, says there are approximately 3,500 IRMA analyzers placed worldwide (80% are in the U.S.) and the business generates about $5 million to $10 million per year. Cohen says the IRMA system will be marketed by ITC in conjunction with ITC's point-of-care coagulation systems. ITC has more than 10,000 coagulation systems placed worldwide and generates nearly $50 million in annual revenue.

Diametrics' IRMA system had been distributed by Philips Medical Systems, which is part of Royal Philips Electronics (Amsterdam, The Netherlands), and Philips will continue to service existing placements until October 2004. Cohen believes that ITC will be able to provide the IRMA system with a more focused marketing approach. He says ITC's current 14-person salesforce will be expanded to 20 by the end of the year.

In addition to poor marketing, Cohen believes that the IRMA system had lost share to market leader i-Stat Corp. (East Windsor, NJ) because of IRMA's limited test menu, which covered blood gas/electrolyte, but not coagulation. He says the combined ITC and IRMA analyzers will offer a broad menu and will be linked through a single data management system that can be connected to hospital LIS systems.

Meanwhile, Diametrics says that it will now focus on its continuous monitoring business, which includes its TrendCare continuous blood gas monitoring system and its Neurotrend cerebral tissue monitoring system.

Stratagene To Acquire Hycor Biomedical

Stratagene (La Jolla, CA) has agreed to acquire Hycor Biomedical (Garden Grove, CA) in a move that will create an IVD company with more than $85 million in combined annual revenue, including roughly $20 million from Hycor and $65 million from Stratagene. Terms call for Hycor shareholders to receive 0.6158 of a share of Stratagene for each share of Hycor. After completion of the deal (expected by year's end), Hycor shareholders will own approximately 23% of the combined company, which will continue to trade on the Nasdaq.

The merger will bring together the privately held Stratagene, which is focused on molecular diagnostics, with the publicly traded Hycor, which generates most of its revenue from its Kova Microscopic Urinalysis System and sales of allergy diagnostics.

Joseph Sorge, M.D., chairman and chief executive of Stratagene, will retain his positions at the combined company. J. David Tholen, currently Hycor president and chief executive will resign and become a member of the combined company's board.

Efficiency–Improving Products Showcased At AACC

The 55th Annual Meeting of the American Association of Clinical Chemistry (AACC) Clinical Lab Expo attracted more than 18,000 attendees to the Philadelphia Convention Center, July 22-24. The exhibit hall was packed with a record 1,485 IVD vendor booths and, as usual, was dominated by the huge displays set up by the major manufacturers.

New product previews and introductions from the majors were aimed at helping labs cope with the ongoing medical technologist shortage (see p. 12) and focused on consolidated workstations for routine chemistry/immunoassay, Internet-based remote diagnostic services, and consulting services aimed at improving lab efficiency. Highlights from the exhibits from six major (plus one interesting smaller) IVD companies are presented below.

Among the suspended immunoassays, Abbott says vitamin B12, folate, and ferritin are on its priority list to bring back first

The sales executives at the booth for **Abbott Diagnostics** (Abbott Park, IL) spent a lot of their time explaining to customers why Abbott failed its FDA inspection last year and why the outcome will be different next time. Don Braakman, spokesman for Abbott, said that Abbott made its quality system documentation too long and complex on the last inspection. On this go-round, Braakman says, Abbott is overhauling its whole manufacturing process and quality control system at its Lake County diagnostic plant with the goal of making it simpler and more systematic.

Braakman says Abbott remains on track to be ready for another inspection by year's end. It will then be up to the FDA to schedule an inspection and file a report. *DTTR* observes that probably the earliest that Abbott will be able to reintroduce assays suspended by the FDA consent decree (assuming the go ahead by the FDA) would be mid-2004.

Meanwhile, Braakman says Abbott is going out of its way to assure customers that it is committed to its AxSym system and will continue to make upgrades and improvements to it. Along these lines, Abbott previewed an Internet-based remote diagnostics system at AACC. The system will be marketed under the tradename AbbottLink and will give Abbott instruments the ability to send and receive operational data, enabling the company's service reps to proactively identify potential technical problems from a remote location. The system was developed using device relationship management (DRM) software made by Axeda Systems Inc. (Mansfield, MA) and will be available on AxSym systems this September and on Architect systems next year, according to Braakman.

Dade Behring (Deerfield, IL) made a splash at the convention by taking out a full-page advertisement in the money section of the *USA Today* on July 23. Dade also plastered the baggage claim areas of the Philadelphia airport with ad posters on the week of the convention. Randy Daniel, president, North America customer management, says that Dade is in the early stages of a corporate branding program aimed at heightening public awareness of Dade and the laboratory testing industry in general.

Dade's next-generation chemistry/immunoassay system—Dimension Vista—

was on display at the company's booth in the exhibit hall. Commercialization is expected to begin in mid-2005 with a menu of more than 100 tests, including vitamin B12, folate, ferritin, hemoglobin A1c, and proBNP, according to Daniel. The broad menu should eliminate one knock on Dade's Dimension series of analyzers, which has been its limited menu, *DTTR* observes. Daniel adds that within two or three years after initial launch, Dade aims to expand the menu on Dimension Vista to 150 to 180 tests.

Ortho-Clinical Diagnostics (OCD—Raritan, NJ) is "aggressively investigating" ways that it can bring a BNP test to market, according to Catherine Burzik, president. She also notes that OCD has just begun rolling out an Internet-based remote monitoring service for the company's Vitros Eci immunoassay systems. The system, which was developed internally, will automatically and continuously monitor the vital signs (temperature, voltage, calibration, etc.) for Vitros Eci analyzers and alert an OCD service office of potential problems.

OCD has just launched a new remote monitoring service for its Vitros Eci system

Dominique Fuzier, product director of worldwide marketing, information technology and eSolutions at OCD, says the remote monitoring service will also be available on the Vitros 5,1 FS Chemistry System, which is pending clearance from the FDA. The Vitros 5,1 FS combines OCD's dry film technology with wet chemistry capability and will integrate up to 80 routine and special chemistry assays.

OCD was also touting its ValuMetrix Services, a fee-based consulting service that was launched three years ago to help labs integrate "lean thinking" and six sigma techniques into their operations. Thirty-five labs have used the service to date, and OCD claims the program has helped these labs cut a total of $25 million in annual costs.

The executives at the booth for **Roche Diagnostics** (Basel, Switzerland) had to contend with customer questions surrounding the company's continued access to Igen's immunoassay technology as well as rumors that Roche was going to acquire Igen to settle the matter. These questions were resolved several days later when Roche officially announced an agreement to buy Igen for $1.4 billion (*see page 1*).

Meanwhile, Dick Aderman, senior vice president and general manager of Roche molecular and centralized diagnostics, North America, told *DTTR* that the company now has more than 150 customers using its proBNP test, which was launched late last year. Aderman says that proBNP is the fastest-selling test he has seen in at least the past seven years. He says that most customers are hospitals adding the test to their menu for the first time, but some are conversions from Biosite's Triage BNP Test.

Roche says its new proBNP test is among the fastest-selling tests ever at the company

Key initiatives at Roche include speeding the rate of adoption of the company's PCR technology at hospitals and regional independent labs, according to Aderman. Currently, there are 600 labs worldwide licensed to use PCR, including approximately 250 in the U.S. Aderman says Roche is aiming to more than double its PCR revenues (currently at about $700 million per year worldwide) within the next three years. The key will be convincing hospitals that the faster turnaround times provided by onsite PCR testing can reduce patient hospital stays, he notes.

Roche is pushing to expand the number of hospital labs that use its PCR technology

Finally, Aderman noted that Roche is pushing to expand its professional services business to hospitals. Dubbed Healthcare Solutions from Roche Diagnostics, the program features an array of consulting services in the area of activity-based cost accounting, strategic planning, outreach marketing, and information technology services.

Bayer Diagnostics (Tarrytown, NY) is working to build up its nucleic acid diagnostics (NAD) business (currently estimated by *DTTR* at more than $50 million per year), according to Joe Wilson, vice president, sales and marketing, corporate accounts/NAD.

The $61 million acquisition of Visible Genetics (Toronto, Canada) completed late last year added approximately $20 million in annual sales to Bayer's molecular diagnostics business, although Wilson notes that sales of VGI's FDA-cleared Trugene HIV-1 genotyping assay are growing a bit slower than anticipated.

Wilson says the biggest challenge for Bayer's 17-person NAD sales team is getting potential clients to realize that there are alternatives to Roche's PCR-based tests. He says Bayer's branched DNA (bDNA) signal amplification technology offers several advantages when compared with PCR, including the ability to run tests directly on serum or plasma samples with no need for sample extraction or purification.

Bayer recently received FDA clearance for its Versant hepatitis C viral load test. The Bayer System 340 (bDNA) now has a menu that includes FDA-cleared viral load tests for HIV and HCV, and a research-use-only HBV viral load test

The emphasis at **Beckman Coulter** (Fullerton, CA) is on the immunoassay market where the company has beefed up its research budget, according to Jeff McHugh, vice president, diagnostics commercial operations, Americas. Beckman recently entered the high-volume immunoassay market with the launch of its DxI 800 Access system (*see DTTR, August 2003, p. 1*). And Beckman is now working to expand its immunoassay menu, which, at about 40 tests, is a little bit behind the curve, according to McHugh. He says that Beckman plans to launch four new immunoassays this year, 13 next year, and another 15 in 2005. "This is a big opportunity for us. Abbott has disappointed its customers and is asking for forgiveness," says McHugh.

Immunoassays slated for launch within the next 12 months include an automated BNP test licensed from Biosite. McHugh says Access customers currently using the Biosite point-of-care BNP tests are eager to make the switch to an automated platform.

Among the hundreds of smaller IVD companies on the AACC exhibit floor was **Quantimetrix Corp.** (Redondo Beach, CA), which was showcasing its Lipoprint test. Expanded lipid profile testing is hot and Quantimetrix is currently the only IVD company on the market with an FDA-cleared test that measures LDL, or bad cholesterol, subfractions. The Lipoprint system sells for $15,000 and each test kit sells for $15 each, according to Nehemias Muniz, director of the electrophoresis division at Quantimetrix. The Lipoprint systems allows labs to bring testing in-house that is otherwise now generally sent out to niche esoteric testing labs like Atherotech (Birmingham, AL) or LipoScience (Raleigh, NC), which have each grown like gangbusters over the past few years due to growing recognition that the traditional cholesterol panels are inadequate measures of heart-disease risk.

DiaDexus Gets FDA Clearance For PLAC Test

DiaDexus Inc. (South San Francisco, CA) has received clearance from the FDA to market its PLAC Test as an aid in predicting an individual's risk for coronary heart disease (CHD) in conjunction with clinical evaluation and patient risk assessment.

The test works by measuring an enzyme called lipoprotein-associated phospholipase A2. This enzyme is made by a type of white blood cell called a macrophage. Macrophages make more of this enzyme and release it into the blood when a person has CHD.

The FDA says it cleared the test based on results of a study of more than 1,348 patients. The study was part of a multi-center epidemiologic study sponsored by the National Heart, Lung, and Blood Institute. Patients were free from CHD at the start of the study and were followed for the development of disease for nine years. The greatest increased risk was found in subjects with the highest PLAC Test results and LDL cholesterol levels lower than 130mg/dL.

The PLAC Test is the first product developed by DiaDexus to receive FDA clearance. Mayo Medical Laboratories (Rochester, MN) is currently offering the test, and Quest Diagnostics recently announced plans to add it to its reference menu as well, Patrick Plewman, chief executive of DiaDexus, tells *DTTR*. He says that DiaDexus has not finalized the price it will sell PLAC Test reagent kits for yet.

Becton Dickinson Slashes Blood Glucose Monitoring Expectations

Becton Dickinson (Franklin Lakes, NJ), which entered the blood glucose monitoring market in March (*see DTTR, February 2003, pp. 1-2*), says a delay in its marketing programs has caused it to slash its revenue estimates for this new market. Through June 30, Becton says it has generated about $8.6 million from its blood glucose monitoring (BGM) business, which includes two FDA-cleared products: the BD Logic Blood Glucose Monitor and the BD Latitude Diabetes Management System.

For the full fiscal year (ends September 30), Becton had expected to book $40 million to $50 million of BGM sales, but it now expects only $15 million. Furthermore, the company now does not expect to achieve break-even operating results from BMG until sometime in fiscal 2005, or a year later than initially anticipated.

On a brighter note, Becton recently announced that the FDA had cleared its Paradigm Link Blood Glucose Monitor. The product combines an insulin pump made by Medtronic Minimed (Northridge, CA) with a Becton glucose meter and facilitates data interchange between the two. The system works like this: 1) a patient performs a blood glucose test using the Becton meter; 2) the test results are automatically transmitted using wireless technology to the patient's Medtronic insulin pump; 3) the insulin pump calculates the proper dosage; and 4) the patient presses a button and the calculated dosage is administered.

Meanwhile, the largest blood glucose monitoring vendor, Roche Diagnostics, reports that its diabetes business grew by 4% to 1.28 billion Swiss francs (US $950 million) in the six months ended June 30, 2003. After adjustments for currency fluctuations, Roche says growth was 14%.

FDA Clears First Test For West Nile Virus

The FDA has cleared the first test for use as an aid in the clinical laboratory diagnosis of West Nile virus (WNV). The test, manufactured by PanBio Limited (Windsor, Australia) is intended for use at hospital and commercial laboratories (not blood screening centers).

The PanBio test works by detecting the levels of a particular type of antibody, IgM, to the disease in a patient's serum. IgM antibodies can be detected within the first few days of the onset of illness. The test was evaluated using over 1,000 patient samples, which were tested at four different clinical sites. The test correctly identified the IgM antibody in 90% to 99% of WNV disease cases. PanBio is selling the test at a price of $6 each, or $576 per 96-test kit, according to Carl Stubbings, senior vice president at PanBio.

PanBio, which has a U.S. headquarters in Columbia, Maryland, specializes in the development and marketing of tests for more than 27 infectious diseases, including Dengue Fever, glandular fever (EBV), and whooping cough. The company has 75 employees and worldwide revenue of approximately $11 million per year.

Meanwhile, Roche and Gen-Probe have each separately developed nucleic-acid tests for WNV for use at blood screening centers. Both tests were authorized for use by the FDA earlier this year under the agency's investigational protocols.

Finally, the Centers for Disease Control and Prevention in Atlanta say that 42 cases of WNV and one death have been reported year to date in the U.S. through July 29. These figures exceed the comparable figures from the same time period last year. In total last year, there were a record 4,156 WNV cases in the U.S., including 284 deaths.

Inverness To Buy Apogent's Point-Of-Care Business For $27M

Inverness Medical Innovations (Waltham, MA) has agreed to purchase Applied Biotech Inc. (San Diego, CA) from Apogent Technologies (Portsmouth, NH) for $27.3 million, including $13.4 million in cash plus 692,506 shares of Inverness valued at approximately $13.9 million. The acquisition is expected to close in August.

Applied Biotech, which generates about $30 million per year in revenue, manufactures rapid point-of-care tests under the brand name "SureStep." Key products include tests for pregnancy, ovulation, menopause, Strep A, H. pylori, and infectious mononucleosis.

Ron Zwanziger, chief executive of Inverness, says Inverness aims to benefit from the addition of Applied Biotech through product and distribution synergies with Inverness' newly acquired Wampole Laboratories business.

Separately, Inverness reports that for the six months ended June 30, the company earned net income of $7.6 million, compared to a net loss of $37.9 million for the same period a year earlier; revenues were up 47% to $130.5 million, with most of the growth due to the recent acquisitions of Wampole and IVC Industries.

■ **With Its Back Against The Wall, Roche Buys Igen,** *from p. 1*

To preserve its lucrative and fast-growing immunoassay business, and perhaps much of its entire IVD business, Roche will pay a total of $1.4 billion for Igen. That seems like a lot especially when you consider what $1.4 billion will buy you these days, *DTTR* observes. Hypothetically, Roche could have used the money to purchase Diagnostic Products Corp., which has a current market cap of $1.1 billion, and had a few hundred million left over to spare.

What $1.4 Billion Can Buy You These Days
(give or take a few hundred million)

Company	*Current Market Cap*
DPC	$1.1 billion
Gen-Probe	$1.3 billion
Bio-Rad Labs	$1.4 billion
Cytyc	$1.4 billion

Source: *DTTR*

But Roche was in a bind. On July 9, the U.S. Court of Appeals for the Fourth Circuit affirmed Igen's right to terminate Roche's license to Igen's Origen technology *(see DTTR, August 2003, p. 1)*. And immediately following the court decision, Igen terminated the license thereby putting Roche's ability to service the 9,000 Elecsys systems it has placed worldwide in jeopardy.

In the days following the appeals court decision, Roche filed for a rehearing, which in all likelihood would not have been granted, and then raced to salvage a deal with Igen. Sources tell *DTTR* that Igen showed absolutely no interest in negotiating another license agreement with Roche, which left Roche with only two options: 1) acquire Igen; or 2) lose access to Igen's technology and face the recall of Elecsys instrumentation, inventory write-offs, and a complete restructuring of its immunoassay business.

In 2002, Roche's Elecsys-based business had sales of approximately 560 million Swiss francs (US $408 million) with a compound annual growth rate in local currencies of approximately 23% over the last three years. And Roche says sales in 2003 are expected to reach about 700 million Swiss francs (US $510 million). With this growing business at stake, plus the potential fallout that a massive product recall would have on Roche's other diagnostics businesses, acquiring Igen was the only logical choice for Roche, observes *DTTR*.

Igen chairman Sam Wohlstadter will get $217 million in cash from Roche for the 4.6 million Igen shares he owns and he'll manage a new spin-off company from Igen

The transaction has been approved by the boards at both Igen and Roche and is expected to close by year's end. Having made such a big commitment, Heino von Prondzynski, head of Roche Diagnostics, has stated that Roche is now aiming to double its share of the immunoassay to 20% within the next few years.

Meanwhile, the deal also calls for the spin-off of a new publicly traded company that will be operated by Igen's current management, including chairman Sam Wohlstadter. This new company, which has yet to be named, will own the patents on Igen's Origen technology and have licenses to Roche's PCR technology in most diagnostic fields. The new company will be free to compete in the entire clinical diagnostics market, including the hospital, blood bank, and reference lab markets, and will also have the right to form strategic partnerships with other companies. So the immunoassay market faces not only increased competition from Roche, but also from the Igen spin-off, *DTTR* observes.

IVD Stocks Up 10% In Latest 3 Weeks Led By Igen

***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 5% at 19.35 euros*

The 21 stocks in the G-2 Diagnostic Stock Index rose an unweighted average of 10% in the three weeks ended July 25, 2003, with 13 stocks up in price and eight down. Year to date, the G-2 Index is up 53%, while the S&P 500 Index is up 14% and the Nasdaq is up 30%.

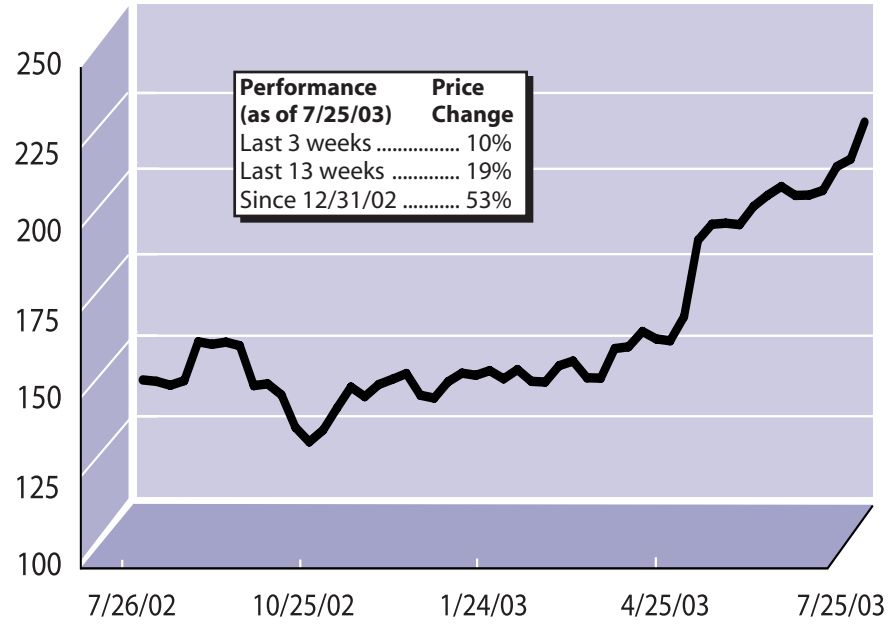
Shares of **Igen International** jumped 76% to an all-time high $59.25 per share for a market cap of $1.6 billion (*see pp. 1 and 10*). At this price, the Igen spin-off is being valued at $12 per share (*i.e.*, $59.25 minus $47.25 for Roche buyout equals $12 for spin-off), or about $320 million.

TheraSense (Alameda, CA) was up 29% to $13.35 per share for a market cap of $547 million. The company recently reported a net loss of $3.5 million for the three months ended June 30 vs. a net loss of $3.1 million for the same period last year; revenue was $50.9 million vs. $59.2 million (or $38.8 million after adjustments).

Gen-Probe (San Diego, CA) was up 24% to $53.99 per share for a market cap of $1.3 billion. The company recently announced that it has filed a 510(k) application with the FDA for its fully automated, high throughput molecular diagnostic instrument, the Tigris DTS System.

Cytyc Corp. (Boxborough, MA) was up 21% to $12.66 per share for a market cap of $1.4 billion. The company recently reported that net income for the three months ended June 30 $18.4 million vs. a net loss of $1.6 million for the same period a year earlier; revenue was up 78% to $76.7 million.

G-2 Diagnostic Stock Index



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

% Price Change, 3 weeks ended 7/25/03

UP	Price	% Chg
Beckman Coulter	42.80	5%
Bio Rad	62.10	5%
Cytyc	12.66	21%
Dade Behring	24.18	4%
Diametrics	1.10	29%
Gen-Probe	53.99	24%
Igen	59.25	76%
Inverness Medical	20.09	4%
i-STAT	9.15	2%
Meridian	10.60	14%
Quidel	6.74	12%
TheraSense	13.35	29%
Ventana	36.70	18%
DOWN		
Abbott Labs	$40.23	-9%
Biosite	46.06	-7%
Diagnostic Products	39.00	-4%
Digene	27.50	-1%
Becton Dickinson	37.40	-5%
Cholestech	9.17	-7%
Immucor	20.80	-7%
Johnson & Johnson	52.23	-1%

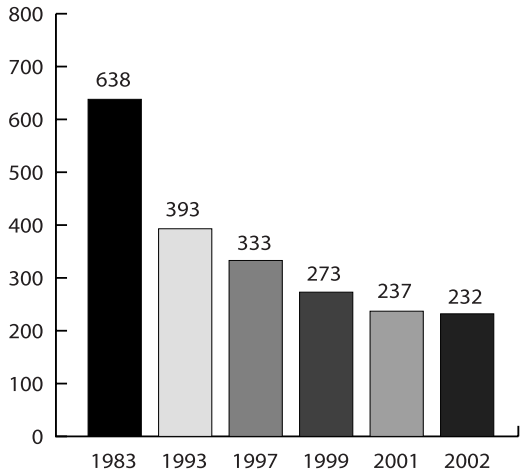
G-2 Insider

Personnel shortages continue to be a major issue for laboratories, and the situation is likely to get a lot worse before it gets better. Vacancy rates at hospitals for staff medical technologists now average 7.2%, while 8.3% of laboratory technician spots are unfilled, according to the latest Wage and Vacancy Survey issued by the American Society for Clinical Pathology (ASCP) Board of Registry.

Of course, IVD manufacturers have long recognized the lab employee shortage and are directing big portions of their research and development budgets towards labor-saving products. Lab automation and workstation consolidation are helping to put off the day of reckoning, but at some point in the future the shortage is bound to become overwhelming.

The average age for medical technologists throughout the country is now near 50 and a huge exodus into retirement is likely to begin within the next five to 10 years. But where will the next generation of medical technologists come from? Because of dwindling enrollments, hundreds of clinical laboratory science programs have been shut down across the nation over the past 10 years. In fact, today there are only 232 colleges, universities, and hospitals in the U.S. offering accredited degrees in clinical laboratory science. That's down by about 30% from the 333 programs that existed just five years ago.

Medical Technologist Programs



Source: National Accrediting Agency for Clinical Laboratory Science

Company References

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