Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

Vol. III, No. 8/April 2003

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WASHINGTON G-2 REPORTS

Established 1979

What Do Lab Managers Want From IVD Vendors?

To get a handle on how the big IVD vendors can improve their service and product offerings to hospital laboratories, *Diagnostic Testing & Technology Report (DTTR)* interviewed 11 lab managers across the country. In spite of the tiny sample size, this anecdotal approach did reveal several trends.

Of course, lab managers want to see no change in reagent prices (unless it's down), and faster service when instrument breakdowns occur is always desired. After these obvious demands, several lab managers tell *DTTR* there is a general need for better communication whenever a reagent formula is changed or an expiration date is shortened.

Several lab managers also tell *DTTR* they are looking forward to the day when all their instruments are connected to IVD technical service offices via the Internet for real-time monitoring of instrument performance and proactive troubleshooting. Vendors say they are feverishly working to develop this technology, which will represent a major advance over the reactive service that is now commonly provided today through phone-modem connections.

For specific comments from the 11 lab managers plus an update on where the IVD industry stands in terms of bringing Internet-based instrument monitoring products to the marketplace, see *Inside The Diagnostics Industry*, pp. 5-8.

TDT Launches $495 Colorectal Cancer Test

Targeted Diagnostics & Therapeutics (TDT-West Chester, PA) says it has begun marketing a new blood test (called GCC-B1) that it has developed for the detection of recurrent colorectal cancer. The "home brew" test is now being performed exclusively at TDT's CLIA-certified laboratory in West Chester. TDT is charging patients $495 for the test, which is currently not covered by Medicare or most third-party payers, according to Arthur Boyce, vice president of marketing. He says the company is directing its marketing efforts at the nation's 6,000 oncologists.

The test most commonly used today for monitoring patients for recurrent colorectal cancer is carcinoembryonic antigen (CEA), a general tumor marker developed almost 40 years ago. Boyce says the main drawback to CEA is that 30% of tumors do not produce CEA at all.

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▲ **Colorectal Cancer Test,** *from page 1*

In addition, Boyce notes that CEA values are subject to influence by other medical and non-medical conditions (such as cirrhosis or even smoking), resulting in high rates of both false negatives and false positives. Thus the test can fail to detect tumors as often as 40% of the time, according to Boyce. On the other hand, *DTTR* observes that the CEA test is relatively inexpensive. For example, Medicare reimburses CEA under CPT code 82378 with a national limitation amount of $26.51.

In contrast, Boyce says that TDT's test is highly sensitive and specific for the detection of guanylyl cyclase C (GCC), which is expressed by colorectal cancer cells found outside the intestine. The TDT method uses RT-PCR to amplify the molecular signal of GCC to determine if it is present in the sample. The test can detect a single cancer cell out of 10 million normal cells, according to Boyce. He points to ongoing clinical trials that show the GCC-B1 test has sensitivity as high as 100% and specificity as high as 91%.

Colorectal cancer is second only to lung cancer in the number of deaths it causes each year. About 163,000 Americans will be diagnosed this year with colorectal cancer and 57,000 people will die from it, according to estimates from the American Cancer Society. There is an estimated recurrence rate of over 40% within five years, and patients are typically monitored throughout that period with CEA tests.

DTTR calculates if the 450,000 Americans who are currently being monitored for recurrent colon cancer were to get one GCC-B1 test per year at a price of $495, the market potential for TDT would total $223 million annually. However, given the expense, this market potential will probably never be realized unless the company can establish reimbursement policies with Medicare and managed care companies.

The test is based on research by Scott Waldman, M.D., Ph.D., a professor of medicine at Thomas Jefferson University (Philadelphia, PA). TDT has entered into a long-term research agreement with Jefferson through which the company is funding Waldman's continuing research-and-development activities. In return, TDT holds the exclusive worldwide rights to the technology.

Since its inception in 1994, TDT has raised about $10 million from private investors and through an equity investment from Millennium Pharmaceuticals (Cambridge, MA), which has licensed TDT's technology to develop new therapies for treating colorectal and other cancers.

LipoScience Hires Brajer As New CEO

LipoScience Inc. (Raleigh, NC), which sells the NMR LipoProfile test for assessing heart disease risk, has hired Rick Brajer as president and chief executive. Brajer was formerly president of Becton Dickinson's clinical laboratory solutions division. He replaces F. Ronald Stanton, who stepped down as chief executive in November after LipoScience announced the loss of its largest client, Quest Diagnostics, and was forced to halt plans to raise as much as $80 million from an initial public offering *(see LIR, October 2002, p. 9)*. A slowdown in business also led LipoScience to cut its staff from 180 employees to 155 earlier this year.

DTTR's Exclusive Interview With Roche's Prondzynski

Heino von Prondzynski

On February 28 in New York City, *DTTR* met with Heino von Prondzynski, head of the diagnostics division at Roche. Our hour-long discussion covered a wide range of topics important to Roche and the IVD industry. Excerpts are outlined below:

What's the latest news on your settlement negotiations with Igen?
There are daily negotiations. We are making progress. If no settlement can be reached, then I am confident that the punitive damages portion [$400 million] of the award will be substantially reduced in the appeals process.

How did the dispute with Igen ever get this far?
Roche did not do everything right. I only joined Roche three years ago and the problems with Igen go back farther than that. There are now a lot of emotions involved. I have a lot of respect for Sam Wohlstadter [chairman of Igen]. If Sam and I could have met earlier, it would never have gotten this far. It's not easy to turn the wheel back.

How much will your AmpliChip CYP450 test cost?
I can't answer that yet, but it will not be a cheap test. [Expensive new molecular diagnostics] are something that people will have to get used to. CYP450 will save lives and save costs.

What is the estimated cost for developing a new diagnostic test to market?
For example, we invested 10 to 12 million Swiss francs [US $7.5 million to $9 million] to bring our proBNP test to market....We anticipate launching our HPV DNA test in ASR form in the U.S. in the first half of 2004 and that has cost 20 million to 25 million Swiss francs [US $15 million to $18.5 million] to develop. Clearly, the value of diagnostic testing must be reconsidered given the investments that are being made.

Roche has had success with TV advertising for its Accu-Chek Compact blood glucose meter. What are prospects for direct-to-consumer advertising for other diagnostic tests?
We placed a worldwide total of one million Compact meters last year [one half in the U.S.] with the help of national TV advertising. It's quite expensive, but it's paying back....But TV advertising for other diagnostics doesn't make sense. Diabetes is widespread and patients can make a direct purchase at a drug store. The same can't be said for other diagnostics.

Operating margins for Roche's glucose monitoring unit exceed 30% and are even higher than the margins for your molecular diagnostics business. How vulnerable are these margins to price competition?
The entrance fee to the diabetes testing market is quite high. Gaining access to customers and creating brand loyalty is not easy. For example, our U.S. sales and marketing staff for diabetes employs 600 people. We have another 120 people in Indianapolis who staff a hot line for meter users 24 hours a day, seven days a week. Putting the infrastructure in place and training all these people takes time.

What are your thoughts on Becton Dickinson's entrance in the glucose meter market?
I'm not scared at all by Becton Dickinson. I believe TheraSense is better positioned to gain share.

US Growth Drivers For Roche In 2002

Top product lines—80% of sales

	USD millions	Growth
1. Accu-Chek Advantage	559	7%
2. Hitachi/Integra	284	10%
3. Cobas Amplicor HCV/HIV	133	9%
4. Applied Science Research	105	7%
5. Elecsys	56	24%
6. CoaguCheck	46	31%
7. Accu-Chek Compact	33	196%
8. AmpliScreen Blood Screening	26	28%
9. Amplicor CT/NG	17	95%

Source: Roche

When might Roche have an artificial pancreas (i.e., automatically tests patient glucose levels and delivers insulin) ready for the U.S. commercial market?
We are looking at the 2008 to 2009 time frame. But keep in mind that an artificial pancreas will never replace the diabetes testing that is done at the moment. It will have its own stake in the market.

What is Roche doing to expand the use of PCR-based testing?
We have a total of 500 PCR accounts globally, several hundred of which are in the U.S. Late last year we launched a PCR program aimed at helping hospital labs train their staff so they can begin PCR testing. Our goal is to get 30 new hospital-based PCR centers operational in the U.S. by the end of this year. [Note: Roche's worldwide molecular diagnostics sales grew by 11% in 2002 to 977 million Swiss francs—US $730 million.]

Who will gain share in the competition to provide lab testing services to physician offices?
I believe the commercial labs will gain share over hospitals over the long term because of their higher level of management expertise. I also see physicians bringing more tests in-house. Simple immunoassays and chemistries will move to physician office labs.

Matritech's BladderChek Found Approvable By FDA

The U.S. Food and Drug Administration has issued to Matritech Inc. (Newton, MA) an approvable letter for the company's NMP22 BladderChek test for use as an aid in diagnosing bladder cancer.

NMP22 BladderChek has already been cleared for monitoring patients with a history of bladder cancer. Cytogen Corp. distributes the CLIA-waived test to urologists for office-based testing. The price per test is approximately $20, and it is reimbursed by Medicare under CPT code 86294 (national limit=$27.41 per test).

BladderChek looks and works much like a home pregnancy test. Using technology licensed from the Massachusetts Institute of Technology (Cambridge), the test detects levels of the nuclear matrix protein, NMP22, in urine. NMP22 is elevated in bladder cancer cells 20- to 80-fold and is released in the urine of bladder cancer patients.

Bladder cancer is one of the most common cancers, with approximately 56,500 new cases and 12,600 deaths in the U.S. per year, according to data from the American Cancer Society. If diagnosed at its early/localized stage, the five-year survival rate is 94%, according to ACS.

Matritech says that its BladderChek point-of-care format can be applied to other cancers such as breast and prostate, and that the company is conducting clinical trials for laboratory-based tests for these cancer types.

Lab Managers To Vendors: "Reduce Instrument Downtime"

Laboratory managers tell *DTTR* that they remain under intense pressure to cut costs and improve efficiency. Compounding the crunch is the widespread shortage of lab personnel. Employee cutbacks are not an answer to meeting tight budgets, and reagent pricing seems to have bottomed out. As a result, lab managers now appear focused on reducing those costs associated with instrument breakdowns and repeat testing. For a closer view, *DTTR* interviewed 11 lab managers and posed the question, "What can IVD manufacturers do to make your life easier?" Here's what they told us:

The lab worker shortage continues to be the key factor that is driving the decision-making process at hospital laboratories. Lab managers are seeking improved or expanded service levels from IVD vendors to help ease the burden of understaffed labs

Joeline Davidson, lab director at West Georgia Medical Center (LaGrange, GA), believes the greatest area of improvement is in instrument error reduction. She notes that her lab currently spends approximately one-third of its budget on labor and supplies related to quality control issues, repeat testing, and troubleshooting (none of which is reimbursable). Cutting lab instrument error rates from the standard 2-3 Sigma (i.e., 308,537 to 66,807 errors per million tests) to 5-6 Sigma (i.e., 233 to 3.4 errors per million tests) would result in immense savings, she notes.

Davidson believes that analyzers with Internet connectivity to the technical service centers of manufacturers are one answer to reducing error rates.

In addition, Davidson says she would like to see that all new analyzers brought to market have the flexibility to interface with lab automation hardware and software from different vendors. The growing lab employee labor shortage will continue to drive labs toward automation, and the ease of interfacing will determine the speed of adoption, according to Davidson.

Luisa Malgerstorfe, administrative lab director for Florida Hospital (Altamonte) and Apopka Hospital (Apopka), says her "ultimate dream machine" is a small analyzer that can perform general chemistry, immunoassay, and therapeutic drug testing on a single platform. She notes that while Florida Hospital has the space for the larger module approach that many vendors now sell, the Apopka Hospital lab, which is about the size of a small bedroom, doesn't have the space. "As the larger health systems continue to acquire smaller hospitals, the desire for smaller analyzers that can be placed across all sizes of hospitals will grow," predicts Malgerstorfe.

Gordon Johnson, director of laboratory and diagnostic imaging at Tillamook County General Hospital (Tillamook, OR), suggests that vendors eliminate the sale of short-dated reagent test kits. These kits are usually sold at full price to smaller labs such as Tillamook, which are often unable to use all the reagents before expiration, resulting in a lot of waste, notes Johnson.

He also sees the need for greater communication between IVD vendors when they change reagent formulas. If a lab is using multiple vendors for instruments, reagents, and quality control materials, then a change in reagent formulation can trigger errors when the quality controls have not been adjusted. This

could be avoided if IVD vendors simply notified one another when formulas were changed, says Johnson.

Finally, Johnson says he'd like to see more lab instruments with interfacing capabilities to manufacturers' service departments. He notes that other hospital vendors, such as diagnostic imaging equipment manufacturers, are far ahead of the IVD companies in this regard.

George Mavros, lab director at Citrus Memorial Hospital (Inverness, FL), estimates that his lab spends 25% of its budget on non-billable services such as calibration, quality control, and instrument maintenance. Like many other lab managers, he believes that direct connections between instruments and vendor service departments are an answer to lowering quality control/maintenance costs and reducing instrument downtime.

Mavros also notes that the cost of service from IVD vendors is "beginning to get out of control." Five years ago, he says, services fees were equal to roughly 5% of the price of a purchased instrument, whereas today they have risen to about 20%. "Most vendors do not respect the fact that hospitals can't pass higher costs on to patients. We have to eat price increases," notes Mavros.

Finally, Mavros says that he'd like to see vendors extend the warranties on purchased analyzers from today's standard of one year.

Jay Wilkerson, administrative director at Community Hospital of Monterey (Monterey, CA), would like to see the major IVD vendors introduce more point-of-care (POC) testing products that correlate with their core lab analyzers. Right now, most of the new POC tests are being developed by smaller companies such as i-Stat and Biosite. Wilkerson notes that many POC tests are not directly comparable to tests run on the big analyzers. "Physicians want test results that correlate regardless of whether they are run at the bedside, outpatient clinic, or in the core lab."

What Can IVD Manufacturers Do To Make Your Life Easier?

Laboratories	***What they want from IVD vendors***
Citrus Memorial	Internet-based remote monitoring, lower service costs, extended instrument warranties
Community Hospital of Monterey	More point-of-care testing products
Eisenhower Medical Center	Keep labs up to date on price changes
Florida Hospital	Chemistry, immunoassay, and therapeutic drug testing on one small platform
Longmont United Hospital	Decrease lot numbers for non-assayed reagents
Mary Lanning Hospital	Hold the line on reagent prices
Reid Hospital	Better communication when reagent/control formulas or expiration dates change
Samaritan Hospital	Limit added admin/shipping expenses when middleman suppliers are cut out
Tillamook County	Longer reagent expiration dates, better communication when reagent formulas change, Internet-based remote monitoring
West Georgia Med. Center	Internet-based remote monitoring, better interfacing capabilities between instruments and lab automation systems
Anonymous independent lab	Faster service to smaller labs

Source: *DTTR* from lab managers

Medical technologists are being stretched thin, and their competency to troubleshoot with new instruments is declining, IVD vendors tell DTTR

Dawn Robertson, lab manager, Longmont United Hospital (Longmont, CO), would like to see vendors decrease the lot numbers on non-assayed reagents to allow for more inter-lab comparisons for quality control.

Christopher Page, diagnostic services director at Mary Lanning Hospital (Hastings, NE), has a simple request for IVD vendors: "Hold the line on reagent pricing."

Frank Allen, lab director at Eisenhower Medical Center (Rancho Mirage, CA), says vendors should notify labs immediately whenever there is a change in reagent prices so they can adjust their budgets accordingly. He notes that his lab recently got a price break because of increased volume, but did not find out until it was invoiced.

Ross Hedgelan, lab director at Samaritan Hospital (Ashland, OH), observes that in order to maintain reagent pricing levels, more IVD manufacturers are selling their instruments and reagents directly to hospitals and cutting out suppliers. This strategy allows the IVD manufacturers to pocket the middleman markups, but it can mean more work for labs, which must deal with more purchase orders and shipping charges.

Chuck McGill, manager of the immediate response lab at Reid Hospital (Richmond, IN), says IVD vendors need to keep their lab customers more informed when they change expiration dates or formulas on reagents and controls.

Finally, a lab manager from Illinois who wishes to remain anonymous, says IVD vendors need to pay greater attention to their smaller customers. She tells *DTTR* that slow problem-fixing help from the field service reps from one major manufacturer forced her lab to rewrite its contract with the vendor. The new contract includes a penalty clause that requires the vendor to pay an hourly fee back to the laboratory anytime an instrument is down for more than eight hours. "Vendors must have a vested interest in your lab's success or failure; otherwise you get placed low on the priority list," she notes.

Beckman's ProService At Forefront Of Remote Monitoring Services

A quick *DTTR* survey of the nation's largest IVD companies suggests that they are gearing up to make Internet-based remote monitoring a standard feature on their high-volume instruments. **Beckman Coulter** (Fullerton, CA) has the lead right now with the recent launch of its ProService program for its Synchron LX20 chemistry systems and Coulter LH 700 series of hematology analyzers.

ProService includes a device relationship management (DRM) software system (made by Axeda Systems Inc.) that is installed on Beckman analyzers. The DRM software automatically and continuously monitors instrument vital signs—such as temperature, voltage, calibration, etc.—and alerts Beckman, via an Internet connection, if an instrument is operating outside preset performance standards. This alert helps service representatives anticipate potential problems and can help in preventing instrument malfunctions. The end result is reduced instrument downtime, Denny Kershner, director of marketing at Beckman, tells *DTTR*.

This "proactive" technology represents a significant step up from the "reac-

tive" phone-modem systems that connect most high-volume instruments today, according to Kershner. He notes that today's phone-modem systems use a "pull" technology that allows IVD service offices to pull data from instruments after a breakdown has occurred. A service representative can then review the data and instruct the laboratory over the phone how to fix the problem.

In contrast, Kershner calls DRM a "push" technology because it automatically monitors an instrument and pushes alerts in front of service reps before the result is instrument downtime. He says that Beckman introduced its ProService program about a year ago at 10 sites and that it has now been installed at 20 locations.

Due to the lab worker shortage, IVD companies say their service reps are being called on to provide additional services, including onsite training sessions, correlation studies, and general troubleshooting

Based on the experience at these 20 sites, Kershner estimates that ProService can eliminate two to three emergency visits per year per instrument. *DTTR* notes that the average high-volume analyzer requires 10 to 12 emergency calls per year, so it looks like DRM technology has the potential to eliminate somewhere between 15% and 30% of instrument breakdowns.

Of course, other IVD companies are also working to integrate DRM technology and Internet connectivity into their instruments. Mike Kerezsi, an engineer at **Dade Behring** (Deerfield, IL), says his company is working with DRM-vendor Questra Corp. (Rochester, NY) to integrate Internet-based remote monitoring into its next generation chemistry/immunoassay platform. Dade hopes to introduce the new platform at the AACC conference this summer. Full rollout is expected sometime within the next two years, according to Kerezsi.

Diagnostic Products Corp. (DPC—Los Angeles, CA) introduced its Internet-based remote monitoring system (called DPC RealTime Service) in mid-2002 for its Immulite instrument systems. DPC is using DRM software from Questra.

Linda Newman, director of marketing of the service division at **Roche Diagnostics**, says Roche has developed a homemade DRM system for its Modular and Integra lines of instruments. The proactive monitoring system will be piloted at 12 labs beginning in the third quarter, according to Newman.

Abbott Diagnostics (Abbott Park, IL) has been working with Axeda Systems since late last year to add Internet-based remote monitoring to its Axsym, Architect, Aeroset, and Celldyne analyzers, according to spokesman Don Braakman. He says Abbott is aiming to introduce the enhanced capabilities for its high-volume analyzers later this year.

Bayer Diagnostics (Tarrytown, NY) is in the process of selecting a DRM vendor so it can add the technology to its high-volume analyzers, Lisa Cherbuliez, director of Bayer's Technical Care Center in Norwood, MA, tells *DTTR*.

Where The Major IVD Vendors Stand With Internet-Based Remote Monitoring

IVD Company	*DRM Vendor*	*Product Introduction*
Beckman Coulter	Axeda	mid-2002
Diagnostic Products	Questra	mid-2002
Dade Behring	Questra	mid-2003
Roche Diagnostics	homegrown	late-2003
Abbott Diagnostics	Axeda	late-2003
Bayer Diagnostics	NA	NA

Source: *DTTR* from companies

Ischemia Gets FDA Clearance For New Heart Attack Test

Ischemia Technologies (Denver, CO) has received clearance from the U.S. Food and Drug Administration to market its Albumin Cobalt Binding (ACB) blood test to help doctors rule out a heart attack when a person arrives at an emergency room with severe chest pains. The test uses the metal cobalt to detect changes in a blood protein that occur during a heart attack. The ACB test is the first new blood test for evaluation of heart attacks since troponin was introduced in 1994, the agency notes.

The ACB test will be sold to labs for approximately $30 per reportable result, according to Robin Daigh, vice president at Ischemia. She says the company is currently working toward getting a unique CPT code for the test so it can be added to the Medicare lab fee schedule.

The ACB test is not a stand-alone heart attack test, FDA cautions, but must be used with an electrocardiogram (ECG) and a troponin test. For every five people who go to emergency rooms each year with heart attack symptoms, only one is actually having a heart attack, the agency says. FDA cleared the test based on clinical trials by Ischemia which showed that when the ACB test was used with an ECG and a troponin test, doctors could rule out heart attack in up to 40% of chest pain patients. Use of ECG and a troponin test alone allows only about 25% of chest pain patients to be safely discharged. Thus, the ACB test has the potential to significantly shorten emergency room lengths of stay and reduce expense for low-risk patients, according to the clinical trials.

Ischemia is a private company founded in 1997 to bring the ACB test to market. To date, Ischemia has invested approximately $20 million to develop the test, with most of the cost related to clinical trials, according to Daigh. Among the venture capital firms backing Ischemia are Wolf Ventures (Denver, CO), Murphree Ventures (Houston, TX), and White Pines Ventures (Ann Arbor, MI).

Daigh estimates that the U.S. market for the ACB test could be as high as $270 million. This is based on data from the National Center for Health Statistics' survey of emergency room visits, which shows that there were approximately six million visits for chest pain in the U.S. in 2000. She says that Ischemia's clinical advisors suggest that the ACB test will be used an average 1.5 times per chest pain patient.

SpectRx Gets $1.4M For Cervical Cancer Detection Device Trials

SpectRx Inc. (Norcross, GA) has received a $1.4 million grant from the National Cancer Institute to support the development of its biophotonic (i.e., spectroscopic) cervical cancer detection device. Mark Faupel, Ph.D., chief technology officer at SpectRx, says the grant will be primarily used to help fund the pivotal clinical trials necessary for FDA clearance of the device. The clinical trials are expected to begin within 90 days and the company hopes to submit a PMA application to the FDA in early 2004, according to Faupel. He says an FDA-cleared product could be on the market in 2005.

The SpectRx device locates cancers and precancers painlessly by shining light on the cervix. Light reflected back from the tissue is analyzed, providing an image of

the cervix. The technology distinguishes between normal and diseased tissue by detecting biochemical and morphological changes at the cellular level. In preliminary studies, the prototypes correlated with histology in the identification of high and low-grade cervical lesions, some of which had been misclassified by Pap tests.

Faupel says SpectRx will first seek clearance of the device for use as an adjunct for abnormal Pap test results. He believes testing on the device, which is intended to be performed by OB/GYNs at office visits, might be reimbursed by Medicare at a level similar to a colposcopy (CPT code 57452; global at $121.39 per procedure). Eventually, Faupel thinks the device could also gain approval for use as a primary cervical cancer screening tool.

SpectRx's first biophotonic product on the market was the BiliChek Non-invasive Bilirubin Analyzer. The BiliChek measures infant jaundice, a common condition in newborns by shining a light on the baby's forehead and then reading changes in the light that are reflected from the skin. The BiliChek is an alternative to the painful "heel stick" blood test for infants and was cleared by the FDA in 1999. SpectRx recently announced an agreement to sell its BiliChek product line to Respironics Inc. (Murrysville, PA), which had been the exclusive licensee and distributor of the device, for $4 million in cash plus up to $7.25 million more from product development, royalties, and earn-out payments to be made over the next five years.

Gentris And Sankyo Establish Partnership

Gentris Corp. (Morrisville, NC) and Sankyo Pharma Inc. (Parsippany, NJ), the U.S. subsidiary of Sankyo Co. (Tokyo, Japan), have signed a three-year, non-exclusive partnership aimed at implementing a pharmacogenomic test panel developed by Gentris to allow Sankyo to better understand the safety and efficacy of drugs it is developing.

Gentris is a privately held company that is developing a CYP450 test for the reference lab market (*see DTTR, March 2003, p. 7*). Sankyo Co. is Japan's second-largest pharmaceutical company, with annual worldwide sales of $4.5 billion.

Roche Sells Drugs-Of-Abuse Testing Line To Varian

Roche Diagnostics (Indianapolis, IN) has announced the sale of its worldwide non-clinical drugs-of-abuse (DOA) testing business to Varian Inc. (Palo Alto, CA). Varian says it paid $22 million in cash for the business, which includes the OnTrak TesTcup, OnTrak TesTstik, OnSite Alcohol, and Intect line of single-use, on-site testing devices.

Roche says the sale was made because the non-clinical DOA testing business is not part of its focus on the clinical laboratory market. Roche says that it is retaining its TesTcard 9 product, which is sold to clinical laboratories, as well as its line of reagents designed for rapid instrument-based drug testing (aka, Abuscreen Online assays).

Varian, which had been a contract manufacturer of the acquired Roche business, is a major supplier of scientific instruments, vacuum technologies, and contract electronics manufacturing services with annual sales of $780 million.

IVD Stocks Up 2% In Latest 4 Weeks; Digene Jumps 45%

***Roche** non-voting equity shares, which trade on the Zurich stock exchange, have fallen 16% to 81 Swiss francs so far this year. Shares of **Bayer**, which trade on the German stock exchanges, are down 40% to 12.31 euros*

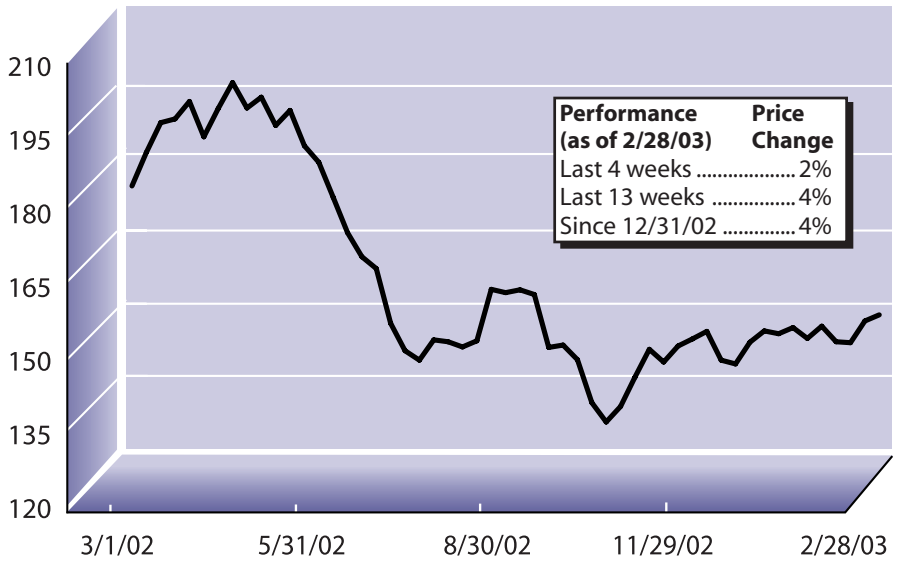
The 21 stocks in the G-2 Diagnostic Stock Index rose an unweighted average of 2% in the four weeks ended Feb. 28, 2003, with 11 stocks up in price and 10 down. Year to date, the G-2 Index is up 4%, while the S&P 500 Index is down 4% and the Nasdaq is unchanged.

Digene Corp. (Gaithersburg, MD) jumped 45% to $16.59 per share for a market cap of $300 million. The company recently reported a net loss of $1.3 million for the three months ended Dec. 31, 2002 vs. a net loss of $1.1 million for the same period a year earlier; revenue was up 25% to $14.5 million. The company says that it continues to work with the FDA in the review of its PMA supplement to permit use of the Digene HC2 HPV Test in conjunction with the Pap test in cervical cancer screening. The test is currently approved for use only as a follow-up for Pap tests with indeterminate results.

TheraSense (Alameda, CA) was up 20% to $8.60 per share for a market cap of $350 million. The company's board recently put in place a stockholder rights plan designed to thwart unsolicited attempts to acquire control of TheraSense at a low price. TheraSense says the plan was not adopted in response to any specific takeover effort, and that it's not aware of any such effort.

Igen International (Gaithersburg, MD) fell 16% to $32.96 per share for a market cap of $782 million. Most of the drop occurred on February 24. This is the date that the U.S. Court of Appeals for the Fourth Circuit (Richmond, VA) heard oral arguments in Roche's appeal of a Maryland district court judge's decision to let stand a jury award of $505 million to Igen. Igen's share price decline suggests that the recent court proceedings did not go smoothly for the company. Note: For the latest comments from Roche's Heino von Prondzynski on the Igen case, *see page 3*.

G-2 Diagnostic Stock Index



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

% Price Change, 4 weeks ended 2/28/03

UP		
Becton Dickinson	$34.40	5%
Beckman Coulter	33.10	3%
Bio Rad	35.95	2%
Cytyc	12.73	10%
Dade Behring	18.65	1%
Diametrics	1.86	18%
Immucor	19.73	5%
Inverness Medical	17.35	7%
Meridian	7.62	1%
Digene	16.59	45%
TheraSense	8.60	20%
DOWN		
Abbott Labs	$35.62	-7%
Biosite	31.27	-13%
Cholestech	6.36	-10%
Diagnostic Products	33.91	-3%
Gen-Probe	24.06	-11%
Igen	32.96	-16%
i-STAT	3.99	-3%
Johnson & Johnson	52.45	-2%
Quidel	3.15	-8%
Ventana	19.41	-10%

G-2 Insider

After years of being shut out of a contract with the nation's largest commercial laboratory, TriPath Imaging (Burlington, NC) has finally gotten its foot in the door. On March 5, TriPath announced a three-year agreement with Quest Diagnostics (Teterboro, NJ) to supply its SurePath test for thin-layer Pap testing to selected Quest laboratories.

The announcement was a blow to Cytyc Corp. (Boxborough, MA) whose exclusive deal to supply its ThinPrep test to Quest expired at the end of 2002. Cytyc and Quest continue to wrestle over pricing terms for a new contract and the TriPath deal could mark the beginning of fairly significant price pressure on Cytyc.

TriPath did not release any information regarding pricing levels for the Quest contract, but *DTTR* estimates that Quest could be paying TriPath less than $6 per SurePath test. That amount is probably $1 to $2 cheaper per test than Cytyc's price to Quest.

Quest, which recently closed on its acquisition of California's largest laboratory (Unilab Corp.), performs approximately 15 million Pap tests per year, accounting for nearly 30% of all Pap tests done in the U.S. Overall, Quest now generates a total of some $4.6 billion in annual revenue, making it the largest single customer for most IVD manufacturers.

Quest's hardball negotiating stance with Cytyc is, of course, not an isolated incident, and its pricing leverage is playing an increasingly important role in the profitability of even the largest IVD vendors.

Correction: The March *DTTR* was incorrectly numbered as issue 6. The correct citation is Vol. III, No. 7.

Company References

Beckman Coulter 714-871-4848
Cytyc Corp. 978-263-8000
Digene 301-944-7000
Gentris 919-465-0100
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LipoScience 877-547-6837
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Diagnostic Testing & Technology Report (ISSN 1531-3786) is published by Washington G-2 Reports, 1111 14th St NW, Ste 500, Washington DC 20005-5663. Tel: 202-789-1034. Fax: 202-289-4062. Order line: 212-629-3679. Website: *www.g2reports.com*

Publisher: Dennis W. Weissman. Editor: D.J. Curren. Managing Editor: Jondavid Klipp, *labreporter@aol.com*