

Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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Labs Are Embracing Web-Based Connectivity, But Many Physicians Still Dragging Their Feet

Hospitals and independent labs are slowly, but steadily, adopting Web-based reporting and order entry and offering the service to their physician clients. Currently, 37% of hospital outreach programs have installed a Web-based connectivity system, according to a survey conducted by the lab services group at Park City Solutions (Ann Arbor, MI). And the same figure for independent labs is probably a lot higher.

But offering Web-based connectivity and getting physicians to actually use it are two different things. The vendors of Web-based systems have recognized this. That's why most have switched their business models away from charging labs on a "per-click" basis toward service fees based on the number of physician connections (not usage).

But with Quest Diagnostics and LabCorp aggressively using their Web-based services as a selling point to physicians, hospital outreach programs and independent labs feel compelled to do the same. For a closer look at the experiences of eight different labs, see *Inside the Diagnostics Industry*, pp. 5-8.

Types of Client Connectivity

Printers	76%
Auto-dial fax	69%
LIS/HIS result inquiry	63%
LIS/HIS for orders	52%
Web-based connectivity	37%
Other	7%

Source: Park City Solutions Third Comprehensive National Laboratory Outreach Survey 2004, n=57 hospital labs

Greenwood Investigation Spreads To HHS, FDA, MPAC

Rep. James Greenwood (R-PA), who is leading a House Energy and Commerce subcommittee that is investigating conflicts of interest at the National Institutes of Health (NIH), has now asked 15 other federal agencies to disclose the amounts, types, and sources of outside funding received by their employees. Among the agencies that have received the request are the Department of Health and Human Services (HHS), the FDA, and the Medicare Payment Advisory Commission, which helps set Medicare reimbursement levels for lab tests. Greenwood's request follows his discovery that NIH scientists had "about 100" outside consulting deals with pharmaceutical and biotechnology companies that were apparently unknown to NIH officials.

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▲ Greenwood Investigation Spreads, from page 1

As part of his growing investigation of the NIH, Greenwood had asked the NIH for information on its scientists' outside consulting activities for the past five years, but the agency was unable to provide a full accounting. Greenwood then sought and got the information from 20 of the largest drug companies. "The concern that there is a substantial number of outside deals that are conducted in total secrecy even from NIH is not implausible," said Greenwood at a June 22 hearing on the matter.

More News on the Correlogic Controversy

Greenwood also provided new details regarding the alleged conflict of interest outlined in a May hearing, in which National Cancer Institute (NCI) researcher Lance Liotta, M.D., Ph.D., and the FDA's Emanuel Petricoin, Ph.D., became paid consultants for a company, Predicant Biosciences, that is in competition with Correlogic, which the two scientists and the NCI were already collaborating (*DTTR*, July 2004, page 1).

Greenwood showed evidence supplied by Predicant that it had paid Liotta a total of \$70,000 for consulting services provided between December 2002 through May 2004. That's significantly more than the \$49,375 that Liotta had reported to NCI ethics officials. The hearing also revealed that Liotta owned a private diagnostic company called Immunomatrix Inc. (Gaithersburg, MD) that has employed Gordon Whiteley, M.D., who is also director of the NCI's clinical proteomics reference laboratory, which is evaluating Correlogic's protein-pattern technology.

Peter Levine, president of Correlogic, testified at the June 22 hearing and in a prepared statement said, "It is impossible in such a Kafkaesque morass to have any hope of impartiality or basic protection of contractual rights such as patent license agreements and CRADA. It is simply wrong for a single federal employee, whose salary is paid by taxpayers, to sit in judgment or influence the outcome of contracts affecting legal rights and obligations when he or she may have private, pecuniary interests."

In response to Greenwood's investigation, NIH director Elias Zerhouni, M.D., said he will tighten ethics restrictions to guard against conflicts, including a total ban on outside consulting by senior NIH officials and anyone involved in awarding NIH research grants, creation of a centralized registry of all outside arrangements, and a public list of the awards that employees may receive.

Long Island Hospitals Plan Large-Scale Study of Correlogic's Test

Despite the distraction of the Greenwood investigation, Correlogic continues to move forward with clinical studies of its protein-pattern recognition technology. To date, several small-scale studies have been published showing that its system has up to 100% accuracy when used to detect ovarian cancer from blood samples. And now the 17 hospitals of the North Shore-LIJ Health System (Huntington, NY) have announced plans for a large-scale validation study that will involve approximately 500 women over a two-year period.

North Shore-LIJ doctors said at a news conference on June 21 that they will attempt to prove that the test, which goes by the brand name OvaCheck, can detect ovarian cancer in its earliest stage.

Correlogic is waiting word from the FDA as to whether it can sell its OvaCheck ovarian cancer test on a homebrew basis.

In addition to ovarian cancer, Correlogic's protein-pattern technology could be used to develop tests for prostate cancer and lung cancer.

The North Shore-LIJ Health System treats more than 11,000 women annually for gynecologic conditions in its hospitals with almost 200 new patients diagnosed with ovarian cancer each year. North Shore-LIJ will initially invite all women undergoing specific gynecologic surgery, women at high risk who are not undergoing surgery, and women who have been diagnosed with ovarian cancer to participate in the study. Later, North Shore-LIJ researchers plan to study women who are at low risk for ovarian cancer.

"This has electrified everyone," said John Lovecchio, M.D., chief of gynecologic oncology for North Shore-LIJ, referring to the possibility that the study could help speed the availability of the test to vulnerable women.

The FDA is currently in the process of determining whether OvaCheck can be brought to market as a laboratory-developed (aka homebrew) test (*DTTR, July 2004, page 8*). If cleared, OvaCheck will initially be aimed at high-risk women and their relatives.

Recently Published Study Shows 100% Accuracy

The North Shore-LIJ study will be the first large-scale study of OvaCheck, although several small-scale studies have already been published. Most recently, the June 2 issue of the peer-reviewed journal *Endocrine-Related Cancer* published "High-Resolution Serum Proteomic Features for Ovarian Cancer Detection," a paper coauthored by Correlogic's chief science officer, Ben Hitt, along with researchers at the National Cancer Institute (NCI) and the FDA. The study showed that Correlogic's protein-pattern recognition technology had 100% sensitivity and specificity in blinded validation tests (68/68 cancer: including 18/18 stage I and 43/43 healthy). 🏠

OraSure's HIV-1/2 Test Gets CLIA Waiver

The FDA has granted OraSure Technologies (Bethlehem, PA) a CLIA waiver for its rapid HIV test to detect both HIV-1 and HIV-2 antibodies by three methods: saliva, blood off a finger stick, and venous whole blood. The waiver will allow more than 100,000 physician office labs, public health clinics, and other sites that are authorized only to perform low-complexity testing to perform OraSure's combined HIV-1/2 test. The combined test had previously only been available in blood form to some 38,000 moderate- and high-complexity labs.

OraSure is expected to price the combined HIV-1/2 test, which is sold under the brand name OraQuick, at an average price of roughly \$10 each. The company says it has the capacity to produce about 300,000 OraQuick products per month. Last year, it sold slightly more than 1 million. OraSure estimates that there are approximately 16.5 million HIV tests performed each year in the United States, including 3.5 million at public health clinics and physician offices.

"We believe this waiver represents the final step needed to make our new OraQuick HIV-1/2 test the most versatile and comprehensive rapid HIV test available to the widest possible range of customers in the United States," said Douglas Michels, OraSure's new president and chief executive officer. 🏠

Ortho-Clinical Licenses Roche's NT-proBNP Marker

Ortho-Clinical Diagnostics (OCD-Raritan, NJ) has been granted a nonexclusive license to use Roche Diagnostic's patented NT-proBNP marker to develop an immunoassay for detecting congestive heart failure (CHF). Under previous agreements, Roche has already licensed NT-proBNP to Dade Behring and Diagnostic Products Corp. OCD is the last major IVD company to gain access to either a BNP or NT-proBNP marker.

BNP testing has been one of the fastest-growing tests in the U.S. immunoassay market for the past three years. The first to market was Biosite (San Diego), which gained FDA clearance for its Triage BNP Test in November 2000. Despite increased competition, Biosite reports that sales of Triage BNP jumped 77% in the first quarter to \$39.2 million. 🏠

BioVeris Sues Executive's Son Over Spending

BioVeris was spun off from Igen International when Igen was purchased by Roche Diagnostics for \$1.25 billion earlier this year.

BioVeris Corp. (Gaithersburg, MD) has filed a lawsuit against its chief executive's son, claiming he and his company inappropriately planned to spend about \$7 million on real estate and luxury cars, according to a company statement.

Jacob Wohlstadter, 34, owns Meso Scale Technologies, which, with BioVeris, jointly owns Meso Scale Diagnostics (MSD-Gaithersburg). Wohlstadter is the son of BioVeris's chairman and chief executive, Sam Wohlstadter, 62. The \$7 million—some of which has already been spent—came from MSD with Jacob Wohlstadter's sole approval and without BioVeris's knowledge, according to the lawsuit, which was filed in the Delaware Court of Chancery on June 14.

Between February 2003 and March 2004, Wohlstadter used funds from the joint venture to buy at least eight cars, including five BMWs, a Dodge Viper, a Land Rover, and an Isuzu sport-utility vehicle, according to an affidavit by BioVeris's chief financial officer, George Migausky. In addition, he placed a \$166,000 deposit on two Ferraris and made plans to build a temperature- and humidity-controlled garage to store the cars. Under Wohlstadter's direction, the joint venture also made a \$630,000 deposit on a \$4.2 million condominium in Manhattan, according to Migausky's affidavit.

The court has granted a motion filed by BioVeris to bar Wohlstadter from spending more than \$10,000 without approval from the joint venture's two-person management board, which includes Wohlstadter and BioVeris's president Richard Massey. BioVeris has also demanded to inspect MSD's accounting records as part of an investigation by its audit committee.

BioVeris, which owns 30% of MSD, has invested \$115 million in the joint venture since 1995, according to court documents. MSD makes drug-discovery instrument systems for pharmaceutical companies and researchers. MSD had product sales of \$3.2 million and a net loss of \$18.2 million in the year ended March 31, 2003 (the latest full-year results available). 🏠

inside the diagnostics industry

Big Labs Driving Move To Web-Based Communications

Web-based connectivity offers big benefits to labs, if they can get docs to use it.

In an effort to keep up with the marketing strategies at Quest and LabCorp, more and more hospital outreach programs and independent labs are adding Web-based solutions to their menu of options that physicians can use to view test results. The demand for these systems is being driven more by a “keeping up with the Joneses” attitude between lab competitors rather than organic demand from physician clients. This means that, in addition to maintaining existing printers and auto-dial faxes, labs now have the added expense of Web-based connections.

And the costs are not insubstantial. Lab executives tell *DTTR* that most labs should expect to pay one-time installation and license fees, ranging between \$50,000 and \$150,000 plus annual service charges of \$60,000 to \$120,000. Those labs that choose to install a “thick-based” system at their large physician-group clients can also expect to pay another \$5,000 to \$10,000 per installation for the cost of the server and related equipment. Finally, most executives strongly recommend that labs hire a full-time Internet specialist to maintain the system and train physician clients and staff on how to use it. Including salary and benefits, labs should budget \$80,000 to \$100,000 for this position, execs advise.

Despite the cost, hospital outreach programs and independent labs are finding it necessary to offer Web-based systems to stay competitive with Quest and LabCorp. For example, Quest reports that 40% of its lab test results are now sent out to physicians via Web-based systems.

But creating Web-based connections to physician clients does not guarantee that physicians and their staff will actually use them. And labs cannot gain the efficiency improvements that the Web has the potential to provide (*see table below*) until physicians get on board.

To increase physician usage, Quest is adding more services to the eMaxx system. Most recently, Quest signed a deal that will allow Express Scripts (St. Louis) to make its pharmacy benefit management services (PBM) available to physicians through Quest’s eMaxx Internet portal. Express provides PBM services to some 50 million members nationwide. Quest already has a similar agreement with Medco Health Solutions (Franklin Lakes, NJ), which has 60 million members.

Some hospitals are taking a similar approach by providing physicians with Web access to inpatient, outpatient, and outreach lab test data and inpatient records.

As with Quest, the goal is to make the combination of information robust enough to convert physicians to the Web.

All lab execs say that the trickiest part of the installation process has always been tying a Web-based system into the variety of office management systems at each physician group. In fact, LabCorp was having so much trouble in this area that it recently purchased Persys Technologies

Benefits of Web-Based Connectivity

- Client retention
- Helps to obtain new physician office clients
- Elimination of uninterpretable orders
- Reduction of data-entry errors on requisitions
- Improves tracking of specimens
- Reduction in phone calls asking for test results

Source: *DTTR* and Park City Solutions

(Virginia Beach), a privately held company whose whole business is focused on providing physician information system interfaces.

An expanded menu of services (lab, pharmacy, inpatient data) and a smooth connection to an existing physician office management system are helpful, but lab execs say the biggest challenge is convincing physicians that the Web is more efficient than traditional paper requisitions and result reports. Overcoming this hurdle requires labs to put themselves in the shoes of their physician clients and, from this viewpoint, select the Web vendor with the system that's easiest to learn and quickest for inputting orders and pulling up results.

A snapshot of what eight different hospital-owned labs and independents are doing with their Web-based connectivity projects begins below:

Spectrum is reaping huge rewards from its Web-based physician office connections.

Spectrum Laboratory Network (Greensboro, NC) might be the most Web-enabled laboratory in the nation. Nate Headley, president, tells *DTTR* that Spectrum, which uses a Web-based system from Atlas Medical (Calabasas, CA), currently has 400 physician clients connected and receives 60% of its test orders through the Web. He says that Spectrum is adding about two new clients per day and 85% of them are getting the Atlas system installed. He's aiming to have 80% of Spectrum's lab orders input by physicians through the Atlas system within one year.

Over the past two years, Headley says that Spectrum has invested well over \$6 million into its Web-based connectivity program, including the development of a touch-screen system for lab orders. Spectrum has 13 FTEs devoted to the maintenance, development, and installation of the Atlas system, he notes. He says that Spectrum monitors use of the Atlas system by client and responds quickly if an installed system is not being used.

It is ease of use that has driven physician usage of lab orders through Atlas, according to Headley. He notes that Spectrum will soon begin providing its larger physician group clients with handheld personal digital assistants (PDAs). These devices will allow physicians to order tests via the Web using either a pen or voice recognition technology.

Spectrum's physicians mainly use the results reporting component to pull up historical results; auto-fax is still the dominant everyday method for viewing test results, says Headley. But that's okay, he says, because the real benefit to the lab is on the order-entry side. As a result of Web-based order entry, Spectrum has seen a reduction in its bad-debt expense and its days in accounts receivable is only 46 days, according to Headley.

Spectrum is a for-profit independent lab that is owned by Moses Cone Health System and High Point Regional Health System. Headley expects Spectrum to grow its revenue by approximately 13% this year to \$90 million. But he says that because of the high percentage of test orders that Spectrum receives via the Web, it will not have to hire any additional front-end accessioning staff to handle the growth.

John Muir/Mount Diablo Health System (JMMDHS-Walnut Creek, CA) currently offers approximately 700 to 800 of its staff physicians a Web-based product from InteHealth (Malvern, PA) that allows physicians to access lab results

Driving physician use of Web-based systems requires an intense and sustained effort on the part of labs.

as well as inpatient health records, according to Scott Liff, executive director of lab operations. He says JMMDHS is developing a system that will automatically send special alerts to physician computers for critical test results.

In addition, Liff says that JMMDHS plans to offer its outreach clients McKesson's Horizon Web-based system for order entry and results reporting this summer. Liff says JMMDHS is also contemplating a more specialized system for its nursing home clients.

Liff advises other labs to carefully analyze the prices each Web-system vendor charges because they vary substantially. "These systems are expensive. You've really got to figure out what they will save you in terms of saved telephone calls and reduced teleprinters. They're not just a cool little toy," adds Liff.

JMMDHS operates two hospital-based labs that perform five million billable tests per year, with approximately 75% coming from outreach.

Affiliated Medical Services Lab (AMSL-Wichita, KS) introduced a Web-based system made by LabPortal.com (Chantilly, VA) about one year ago, according to Edwin Harned, president. He says that AMSL now has approximately 10% of its 1,000 physician office clients connected to the system. Although a handful of physicians have switched back to paper-based systems, the great majority are using LabPortal.com for both order entry and to view or print out results.

Harned attributes AMSL's success in large part to the lab's Internet specialist, whose sole responsibility is managing the Web system and training physician-office clients in how to use it.

He advises labs to seek Web systems that can easily be integrated into LIS systems and update patient demographic data from physician office management systems on a real-time basis. This allows the lab to receive barcoded specimen tubes that can be scanned into the LIS and then placed onto front-end automation system racks. Harned hopes to add these capabilities to his lab within the next year or two.

AMSL, which processes about 2,000 requisitions per day, is a for-profit independent lab that is owned by the Via Christi Health System (Wichita).

Hunter Laboratories (Campbell, CA) is installing a Web-based system from Atlas and hopes to go live within a month, according to Chris Riedel, president. He says having a Web-based system is "instrumental" for competing against Quest and LabCorp.

Riedel says he chose Atlas because of its fast and simple process for physician test ordering. The one drawback is that the Atlas system can't process cash transactions from self-paying customers, so it can't be used at Hunter's PSCs, according to Riedel.

From the physician's standpoint, Riedel believes the biggest benefit of Web-based connectivity is that the physician can build an archive of patient test result data that can be called up at anytime. "Paper records get misplaced or lost. This will eliminate the harsh words between doctors and nurses when records can't be found," he adds.

Many docs still find paper reqs to be faster and easier to use than Web-based systems.

A marketing executive (who wishes to remain anonymous) at a **large commercial lab in the Southwest** tells *DTTR* that, in some circumstances, the company's Web-based connectivity system can be a "big deal" to a physician client, "but in the vast majority it is not." And he adds, "It's not something they ask for on their own."

The biggest obstacle toward greater physician adoption is the fact that he or she can fill out a paper test requisition in one to two minutes versus three minutes for a Web-based order, according to the executive.

He says the one area where Web connectivity is in high demand is in viewing pathology reports. "Local pathologists do like to view timely, high-quality flow cytometry reports over the Web," notes the executive.

Westcliff Medical Laboratories (Newport Beach, CA) is using a number of Web-based systems, including a homegrown system and products from 4Medica (Culver City, CA), according to Rick Nicholson, president. He says that many physicians look at Web-based order entry as a time-consuming step and prefer traditional handwritten ordering. The time involved with training to learn a new system is an issue with physicians. Nicholson says that because of lack of usage, Westcliff has pulled some Web systems out of physician offices.

He says the greatest demand has been from larger physician groups and younger physicians, "who look at the Internet as a necessity." Overall though, Nicholson says that physicians view Web-based communications very low on their list of priorities when selecting a lab. For those physicians that have a choice on where to send their lab work, the emphasis is still on things such as turnaround times, location of PSCs, and the ability to fix problems quickly, according to Nicholson.

Westcliff is a privately held lab with 360 employees, 42 PSCs in southern California, and annual revenue of \$35 million to \$40 million.

SED Medical Laboratories (Albuquerque, NM) has offered a Web-based results reporting system from CareEvolve (Elmwood, NJ) for about one year, according to Jim Fantus, president. He says that SED currently has about 65 physicians connected to the system. He says usage varies from doctor to doctor. SED felt compelled to offer the service because of the marketing efforts of Quest and LabCorp. Fantus says SED is holding off on the order-entry component because it's more complicated to install and get physicians to use. He says that installation, maintenance, and the training involved with offering a Web-based system require that labs hire a full-time information technology specialist.

Sentara Healthcare (Norfolk, VA) plans a full launch of a Web-based results reporting system made by Healthvision (Irving, TX) this fall. The system, which is currently being piloted at 10 medical groups affiliated with Sentara, will allow physicians to look up lab and radiology test results from any Web-connected PC. Healthvision will replace an existing homegrown product that was cumbersome for physicians to use, according to Beth Deaton, business and sales manager at Sentara Lab Services. Deaton says Sentara is currently looking for a separate system for lab order entry. Sentara operates six hospital labs and a reference lab that perform a total of four million billable tests per year, including one-third from outreach. 🏠

Lab Workforce Shortage Eased In 2003, But Long-Term Issues Persist

The lab workforce shortage and associated wage pressures eased last year, according to a survey conducted by the American Society of Clinical Pathologists (ASCP—Chicago). The survey findings mark a big change from the chronic lab personnel shortages that have been reported in the past few years.

The survey, which was based on data from 1,682 lab managers across the country, showed that vacancy rates for staff medical technologists declined from 7% in 2002 to 4.3% in 2003. Over the same time period, vacancy rates for staff cytotechnologists

dropped from 7.6% to 4.3%, while staff histotechnologists vacancies fell from 10% to 3.6%.

The position with the highest vacancy rate in 2003 was staff phlebotomist at 6.6%. Average hourly pay for staff phlebotomists increased by 4.6% to \$11.03; over the past five years, the average annual increase has been 4.2%.

The position with the lowest vacancy rate in 2003 was medical technologist manager

at 1.9%. Average hourly pay for medical technologist managers increased by 5.3% to \$30; over the past five years, the average annual increase has been 4.3%.

Kory Ward-Cook, Ph.D., senior vice president at ASCP, says that the growing use of lab automation systems and workstation consolidation may have contributed to the overall decline in lab vacancy rates. She also notes that several major acquisitions completed by Quest (American Medical Labs and Unilab) and LabCorp (Dynacare and Dianon) over the past two years have resulted in a steady supply of laid-off lab workers available for hire.

Nonetheless, Ward-Cook notes that 40% of ASCP-certified medical technologists are between 46 and 66 years old, with an average age of about 49. Over the next 10 years, many of these people are expected to retire. The lab workforce shortages will hit again. "It's always been somewhat cyclical," she adds. ▲

Average Vacancy Rates for Key Laboratory Positions

Position	2002	2003
	Vacancy Rate	Vacancy Rate
Medical Technologist—Staff	7.0%	4.3%
Medical Technologist—Supervisor	5.9%	3.3%
Medical Technologist—Manager	3.7%	1.9%
Cytotechnologist—Staff	7.6%	4.3%
Histotechnologist—Staff	10.0%	3.6%
Medical Laboratory Technician—Staff	8.6%	5.9%
Phlebotomist—Staff	9.1%	6.6%

Source: American Society of Clinical Pathologists

Median Hourly Pay Rates: 1998 to 2003

Position	1998	2000	2002	2003	5-Year CAGR*
Medical Technologist—staff	\$16.00	\$17.90	\$19.32	\$20.00	4.6%
Medical Technologist—supervisor	19.80	21.50	23.00	24.50	4.4%
Medical Technologist—manager	24.30	27.00	28.50	30.00	4.3%
Cytotechnologist—staff	19.00	21.30	24.00	24.70	5.4%
Histotechnologist—staff	15.60	18.00	19.77	19.67	4.8%
Medical Lab Technician—staff	12.90	14.00	15.35	15.96	4.4%
Phlebotomist—staff	9.00	9.90	10.55	11.03	4.2%

*CAGR=compound annual growth rate

Source: American Society of Clinical Pathologists

Cholestech Gets FDA Clearance For High-Sensitivity CRP

Cholestech Corp. (Hayward, CA) has received FDA clearance for its new high-sensitivity C-reactive protein test cassette. Cholestech says the test can be run on its existing Cholestech LDX System once a simple software upgrade has been completed. This 510K clearance will allow the company to market the product to moderately complex laboratories. Cholestech says it also plans to seek waived status from the FDA for the test.

Separately, Cholestech announced that it has received a CLIA waiver for its aspartate aminotransferase (AST) test, making it the first AST test to gain this classification. The AST test will run on the Cholestech LDX system, in conjunction with the company's alanine aminotransferase (ALT) test, which was waived in 2001.

AST and ALT quantitative measurements are used by physicians to assess the potential for liver damage resulting from therapy with certain drugs and in the diagnosis and treatment of certain liver diseases such as hepatitis and cirrhosis, as well as heart diseases.

Nearly 200 million ALT and AST tests are performed each year in the United States, according to Cholestech. The company anticipates launching a waived ALT/AST test cassette this fall. 🏠

Becton Dickinson To Pay Retractable Technologies \$100 Million

Becton Dickinson (BD-Franklin Lakes, NJ) has agreed to pay Retractable Technologies Inc. (RTI-Little Elm, TX) \$100 million to settle a lawsuit filed against BD in Texas. Retractable Technologies had charged that BD used its dominant market share in blood collection devices to restrict competition in the marketplace. Under the terms of the agreement, the suit against BD will be dismissed with prejudice, BD said in a statement.

RTI manufactures VanishPoint retraction safety syringes and blood collection devices, which virtually eliminate healthcare worker exposure to accidental needlestick injuries. RTI had contended that BD controls over 90% of the market for disposable blood collection tube holders in the United States and was using its dominant market position to force group purchasing organizations (GPOs) and distributors from putting RTI products on their product lists.

Earlier this year, RTI received \$8 million in connection with the settlement agreements reached in the second quarter of 2003 with the GPOs Premier Inc., VHA Inc., Novation, and healthcare-product-distributor Tyco International. BD was also part of the lawsuit, but was unable to reach a settlement agreement until now.

The \$100 million payout that RTI will receive couldn't come at a better time, *DTTR* observes. The privately held company has lost a total of \$42 million since being formed in 1994. In the three months ended March 30, RTI reported a net loss of \$2.7 million versus a net loss of \$1.3 million; revenue declined 3% to \$4.3 million; cash holdings totaled \$5.9 million. 🏠

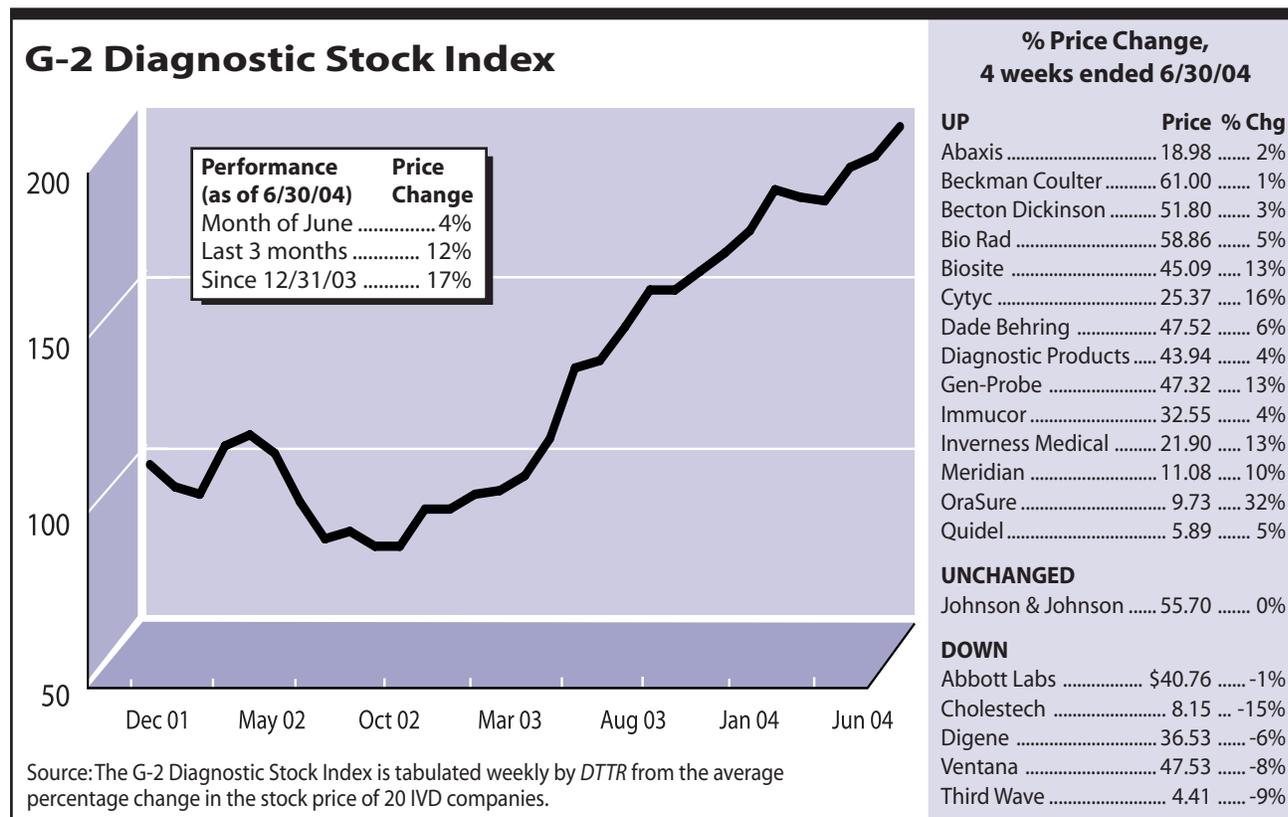
IVD Stocks Up 4%; OraSure Up Big

The 20 stocks in the G-2 Diagnostic Stock Index rose an unweighted average of 4% in the month of June, with 14 stocks up in price, one unchanged, and five down. Year to date, the G-2 Index is up 17%, while the S&P 500 Index is up 3%, and the Nasdaq is up 2%.

The best-performing IVD stock in June was **OraSure** (Bethlehem, PA), which was up 32% to \$9.73 per share for a market cap of \$432 million, or approximately eight times its annual revenue of \$50 million. OraSure jumped on news that the FDA has granted a CLIA waiver for its rapid HIV test to detect both HIV-1 and HIV-2 antibodies (see page 3).

Cytc Corp. (Boxborough, MA) was up 16% to \$25.37 per share for a market cap of \$2.7 billion, or approximately eight times its annual revenue of \$323 million. Shares of Cytc jumped after an analyst at Leerink Swann & Company (Boston) raised his rating on company to "outperform."

Gen-Probe (San Diego) was up 13% to \$47.32 per share for a market cap of \$2.3 billion, or approximately nine times the company's annual revenue of \$250 million. **Inverness Medical** (Waltham, MA) was also up 13% to \$21.90 per share for a market cap of \$450 million, or 1.2 times its annual revenue of \$364 million. In addition, **BioSite** (San Diego) was up 13% to \$45.09 for a market cap of \$680 million, or 2.8 times its annual revenue of \$240 million. 🏠



G-2 Insider

There are well over 1,000 independent lab companies doing business in the United States today and it's hard getting your arms around this segment of the industry. But below we list the 20 largest independent lab companies in the nation ranked by their net revenue for 2003. This information comes from Washington G-2 Reports' forthcoming market research report: *Lab Industry Strategic Outlook 2005*. 🏠

Look for more information on Lab Industry Strategic Outlook 2005 in the next issue of DTR.

Top Twenty Independent Lab Companies 2003

Company	Headquarters	Estimated Revenue 2003 (\$ mill)	Market Share
Quest Diagnostics	Teterboro, NJ	\$4,738	37%
LabCorp	Burlington, NC	2,939	23%
AmeriPath	Riviera Beach, FL	485	4%
LabOne	Lenexa, KS	346	3%
Mayo Medical Labs ^H	Rochester, MN	200	2%
ARUP Laboratories ^H	Salt Lake City, UT	190	1%
Spectra Renal Management	Lexington, MA	150	1%
Clinical Pathology Labs	Austin, TX	145	1%
Impath*	New York City	125	1%
Specialty Labs	Santa Monica, CA	120	1%
Bio-Reference Labs	Elmwood Park, NJ	109	1%
Esoterix	Austin, TX	108	1%
Genzyme Genetics	Westborough, MA	101	1%
MDS (U.S. laboratories only)	Brentwood, TN	100	1%
Spectrum Laboratory ^H	Greensboro, NC	80	—
Gambro Healthcare Laboratory Services	Ft. Lauderdale, FL	75	—
South Bend Medical Foundation	South Bend, IN	75	—
DaVita Laboratory Services	Deland, FL	70	—
TriCore Reference Labs ^H	Albuquerque, NM	65	—
Health Line Clinical Labs	Burbank, CA	60	—
Total, 20 lab companies above		10,281	79%
Other independent labs		2,719	21%
Grand Total		\$13,000	100%

H=hospital-owned independent lab company

*Impath was acquired by Genzyme Genetics in May 2004

Source: Washington G-2 Reports' forthcoming industry report *Lab Industry Strategic Outlook 2005*

Company References

Affiliated Medical Services Lab
316-265-4533
ASCP 312-738-1336
Becton Dickinson
201-847-6800
BioVeris 301-869-9800
Cholestech 510-732-7200
Correlogic 301-214-4030
Hunter Laboratories
408-341-8600
OraSure 503-641-6115
Retractable Technologies
972-294-1010
Spectrum Laboratory Network
336-664-6100
Westcliff Medical Labs
949-646-0216

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