# Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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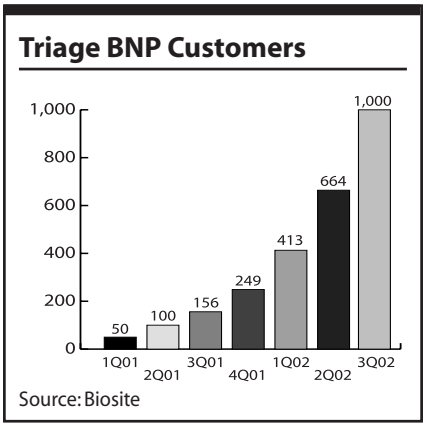
## Market For BNP Testing Is Blasting Off

Diagnostic testing for B-type natriuretic peptide (BNP) is exploding, and right now Biosite (San Diego, CA), which sells the only assay for BNP that has been cleared by the U.S. Food & Drug Administration, is reaping the rewards. The company's Triage BNP Test is a point-of-care blood test that helps doctors determine whether a patient who is short of breath is suffering from congestive heart failure. Triage BNP was launched in the U.S. market in early 2001 and is now in use at more than 1,000 medical facilities. Roughly 100 new hospitals are adopting the technology every month. The overwhelming market acceptance of Triage BNP has been a bonanza for Biosite, which is generating more than $40 million in annualized revenue from the product.

Next year, the outpatient market for BNP testing will get a big boost when Medicare dramatically hikes reimbursement for the test. The current national Medicare fee cap for the test, billed under CPT 83520, is $17.89. In 2003, the test will have a new CPT code (83880) and the fee Medicare has tentatively set for it is approximately $47-$48.




But Biosite won't have the BNP market all to itself for long. Roche Diagnostics plans to launch its competing product, Elecsys proBNP, in the U.S. soon, while Bayer and Abbott each plan to have their BNP tests on the U.S. market within 12 months. For details, see *Inside The Diagnostics Industry*, pp. 5-7.

## IVD Manufacturers Race To Develop Blood Screening Test For West Nile Virus

Roche Diagnostics (Basel, Switzerland), Gen-Probe (San Diego, CA) and BioMerieux (Marcy-l'Etoile, France) are each accelerating efforts to create a nucleic acid test for West Nile virus (WNV) that can be used to screen the nation's blood supply. Because mosquitoes are the most common vector for transmission of the virus, there is enormous pressure to create a viable screening test by next summer, when the mosquito season reaches its peak in the U.S.

*Continued on p. 2*

▲ **IVD Manufacturers,** *from page 1*

*So far this year, the federal Centers for Disease Control & Prevention has recorded 3,495 laboratory-positive cases of West Nile virus and 204 deaths*

Federal health officials now believe it's highly likely that WNV can be transmitted by blood transfusion and are working with blood centers and the diagnostics industry to proactively address what could become a public health emergency next summer. WNV is currently diagnosed in patients using antibody tests. But these tests cannot be used to screen donated blood because the virus lingers in the blood for at least a few days—maybe as long as two weeks—before an infected individual develops symptoms and detectable antibodies. In contrast, nucleic acid tests look for the virus itself in the blood and thus can detect its presence earlier.

"What we're trying to do is to jump-start and facilitate this process, so we can get a test available as soon as possible to screen blood, if that is needed. In doing this, FDA can utilize its regulatory authority to allow use and evaluation of a screening test in a public health setting even before it meets requirements for licensure," said Jesse Goodman, MD, head of FDA's Center for Biologics Evaluation & Research, during a Sept. 19 conference call with the media.

Development of an FDA-cleared assay for screening the nation's blood supply could bring with it a huge windfall, given that roughly 15 million blood donations for transfusion are made in the U.S. each year. Using the pricing history for nucleic acid testing for HIV and hepatitis C, Jim MacPherson, chief executive of America's Blood Centers (Washington, DC), estimates that a WNV test cleared for investigational use only (IUO) would equate to $5-$7 in revenue per test to the IVD manufacturer. This figure would probably double, MacPherson adds, once full licensure is granted. Thus, nucleic acid testing for WNV could ultimately become a $150-$210 million annual market for the test makers.

With promises from FDA to expedite the approval process, plus the potential of a $150-$210 million market, it's no wonder that Gen-Probe, Roche and BioMerieux are all racing to develop a nucleic acid test for WNV.

Gen-Probe recently announced that it has received a $1 million contract from the National Heart, Lung & Blood Institute within the National Institutes of Health to develop a nucleic acid screening test for WNV. Larry Mimms, Gen-Probe's vice president for strategic planning and business development, says the company expects to be ready with an IUO product by next summer.

Separately, Roche has announced its goal to have a PCR (polymerase chain reaction) assay to screen blood donations for WNV ready for FDA review by the second quarter of 2003.

At BioMerieux, clinical marketing manager Lynell Grosso tells *Diagnostic Testing & Technology Report* (*DTTR*) that the company has already developed a WNV test kit for use on its NucliSens analyzer, but it is not yet FDA-approved. A version of the test is being used by laboratories in Florida and North Carolina for surveillance of mosquito pools and birds. BioMerieux is aiming to adapt this test to a clinical assay that can be used for blood screening, she says.

Meanwhile, the blood banking industry and FDA are looking at the role of pathogen inactivation as a potential solution for WNV and other emerging pathogens that may be transmitted through the blood supply. One company developing patho-

gen inactivation products is V.I. Technologies Inc. (Bethesda, MD), whose "Inactine" technology is in Phase III clinical trials.

In addition, Cerus Corp. (Concord, CA) has developed the Intercept Blood System in collaboration with Baxter Healthcare Corp. (Deerfield, IL). This pathogen inactivation system recently received European and Canadian regulatory approval and is now in Phase III clinical trials in the U.S.

## Head Of Bayer's HealthCare Unit Quits, Classon Now In Charge

Bayer Group (Leverkusen, Germany) has announced that Frank Morich, MD, head of its healthcare unit, has left the company "by mutual agreement." The resignation was effective immediately and suggests there may have been some differences of opinion over the direction of the struggling unit, which generates annual revenue of nearly 10 billion euros (US $10 billion) and includes pharmaceuticals, over-the-counter drugs and diagnostics operations. Morich, 49, had been with Bayer for more than 20 years.

Late last year, Bayer announced plans to transform its organizational structure into a management holding company with four legally independent corporate units for healthcare, agrochemicals, polymers and chemicals. The new structure will become effective Jan. 1, 2003. Analysts say it will facilitate a major overhaul of the conglomerate that could include divestitures, mergers or joint ventures. For several years now, investors have been pressuring Bayer to either sell or spin-off its healthcare unit (*DTTR, Apr. 01, p. 1*).

*Rolf Classon*

Bayer says Rolf Classon, 57, is now the chairman of Bayer HealthCare. Prior to Morich's resignation, Classon had been slated to step down as head of Bayer Diagnostics (Tarrytown, NY) to become head of strategy and development at Bayer HealthCare, effective Jan. 1, 2003.

Bayer spokesman Günter Forneck tells *DTTR* there is no link between Bayer's ongoing review of its strategic options for the healthcare unit and the appointment of Classon. Forneck declined to answer questions about possible strategic moves for Bayer.

Meanwhile, Bayer has named Wolfgang Hartwig, PhD, as head of Bayer Diagnostics, effective immediately, to fill the spot left open by the promotion of Classon. Hartwig had formerly headed global research activities of Bayer's Pharmaceuticals Business Group and had been expected to become head of the diagnostics unit at the beginning of next year (*DTTR, Aug. 02, p. 9*).

## OraSure Receives FDA Clearance For Rapid HIV-1 Test

OraSure Technologies (Bethlehem, PA) has received approval from the U.S. Food & Drug Administration for its OraQuick Rapid HIV-1 Antibody Test, a point-of-care test that detects antibodies to HIV-1 from a fingerstick whole blood sample within 20 minutes with 99.6% accuracy, the government announced on Nov. 8. Positive test results still must be confirmed by separate, specific testing. Moreover, the test is not approved to screen donated blood.

**OraSure In Brief** *($000)*

| | Nine months ended 9/30/02 | 9/30/01 |
|---|---|---|
| Revenue | $23,762 | $24,510 |
| Net income | -3,261 | -1,425 |
| Cash holdings | 13,368 | 15,707 |
| Long-term debt | 3,479 | 3,830 |

Source: OraSure

With FDA approval, OraQuick will be available for sale to the nearly 40,000 laboratories in the U.S. that are certified under CLIA (Clinical Laboratory Improvement Amendments) to perform moderately complex diagnostic tests. In addition, Michael Gausling, chief executive of OraSure, says the company has been encouraged by FDA to seek a CLIA waiver for the test and is now working to do so (*see p. 12, this issue*).

OraSure will jointly distribute the test in the U.S. with Abbott Laboratories under an agreement signed earlier this year (*DTTR, July 02, p. 8*). Sales from OraSure to Abbott are expected to begin in the next 30 to 60 days. Abbott spokesman Don Braakman tells *DTTR* that Abbott will set pricing to end-users at somewhere below $20 per test.

Braakman notes that the OraQuick test is not the first rapid HIV-1 test—a 10-minute version called SUDS (single use diagnostic system) has been sold by Abbott since the late 1990s. Abbott gained the technology through its acquisition of Murex Corp. (Norcross, GA) in April 1998. However, the Murex test was so difficult to use accurately that many health clinics abandoned it. Braakman says OraQuick is much simpler to use. Abbott is also the leading provider of traditional blood-based HIV-1 test kits for the central laboratory.

The biggest potential market for the OraQuick test may be public health clinics, where an estimated 2.5 million HIV-1 tests are provided each year. However, routine HIV-1 testing today requires that specimens to be sent to a laboratory, so an individual must make a return visit to get test results. According to statistics from the U.S. Department of Health & Human Services, some 25%-30% of public health clinic patients never return to get their test results and 8,000 of these no-shows test HIV-positive.

Gausling sees other markets where the OraQuick test has great potential, including the military, which wants a rapid test for battlefield use, and hospitals that want a fast way to tell whether health workers have been infected by needlestick accidents.

FDA clearance of OraQuick should give a needed boost to OraSure's financial condition. In the nine months ended Sept. 30, 2002, the company reported a net loss of $3.3 million vs. a net loss of $1.4 million for the same period a year earlier; revenue fell to $23.8 million from $24.5 million.

## Dade Behring CEO Jim Reid-Anderson Named Chairman

Dade Behring (Deerfield, IL) says its board of directors has unanimously elected Jim Reid-Anderson, the company's president and chief executive, to the additional position of chairman. Reid-Anderson was initially appointed president and CEO of Dade Behring in September 2000. Over the past two years, he has helped the company complete a wide-ranging restructuring that culminated in this summer's Chapter 11 reorganization, which reduced company debt by approximately 50%, and has been followed by a listing of its shares on the over-the-counter market.

inside the diagnostics industry

# Competition Revs Up For The Emerging BNP Testing Market

*The U.S. market for diagnosing and monitoring congestive heart failure by BNP testing could easily exceed $200 million annually within the next 3-5 years,* DTTR *estimates*

Congestive heart failure (CHF) is a chronic inability of the heart to maintain an adequate output of blood from one or both ventricles, resulting in congestion or swelling of certain veins or organs and an inadequate supply of blood to the body. As a result of this poor circulation, blood and fluid begin collecting in organ tissue. The primary symptoms of CHF are swelling of the legs and arms and shortness of breath.

Nearly five million Americans live with CHF, the American Heart Association estimates. Every year, 550,000 new cases are diagnosed. Fifty percent of those with CHF die within five years of being diagnosed. CHF is the single most common cause of hospitalization in the U.S. for patients older than 65, with more than one million hospitalizations each year.

The current "gold standard" for diagnosis is the echocardiogram. Its accuracy, however, is highly dependent on the expertise of the person administering the test. In addition, echocardiograms typically cost between $400-$800 per procedure and are not always readily available in all hospitals.

In November 2000, Biosite (San Diego, CA) received clearance from the U.S. Food & Drug Administration to market the Triage BNP Test, the first and only blood test currently approved in this country as an aid in the diagnosis of CHF. The Triage BNP measures levels of B-type natriuretic peptide, or BNP, a hormone that is elevated in patients suffering from heart failure. The test runs on a portable analyzer that provides results in about 20 minutes on whole blood specimens. Biosite says its test can reduce time to treatment for CHF patients and improve emergency department efficiency.

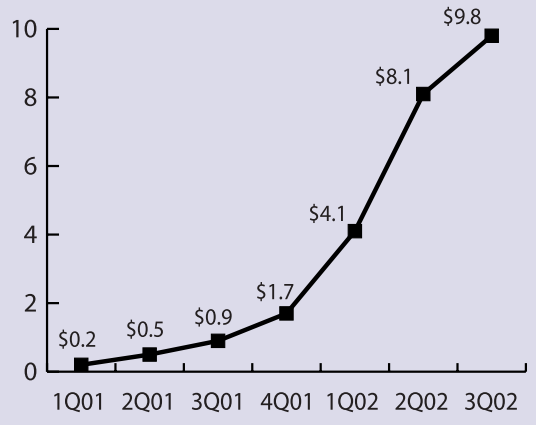
Biosite commenced marketing of its Triage BNP Test in December 2000. Fisher HealthCare distributes it to U.S. hospitals. Biosite sells the test to Fisher for approximately $18 and Fisher marks it up to hospital customers to approximately $25 per test. The portable analyzer that runs the test has a list price of $4,600.

*Higher Medicare reimbursement for outpatient BNP testing is likely to spur such testing at cardiologists' offices and clinics*

The Triage BNP Test for inpatients is reimbursed by Medicare under the Part A diagnosis-related groups (DRGs). More than 1,000 hospitals currently use the test; average utilization per hospital is 6-7 tests per day. Approximately 25% of the volume is currently performed at point-of-care locations (primarily hospital emergency departments and heart failure clinics); about 75% is performed at hospital central laboratories.

To date, the market for outpatient BNP testing has been limited largely because of low Medicare reimbursement. Currently, such testing is reimbursed under CPT code 83520 (immunoassay, not otherwise specified), whose fee is capped nationally at $17.89. This will change significantly next year. The Centers for Medicare & Medicaid Services has recognized a new CPT code, 83880, for BNP testing with a tentative fee determination of approximately $47-$48. If this fee determination is finalized, it will make it the procedure economical for outpa-

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




Source: Biosite

tient testing and should encourage test volume growth in these locations.

As a result, Biosite says it is preparing to greatly expand its distribution capabilities to the outpatient market. Also, Biosite says it has completed a clinical trial and submitted data to FDA to obtain a CLIA waiver for Triage BNP. Gaining waived status would allow the Triage BNP test to be sold for at-home testing by patients with a prescription, the company adds.

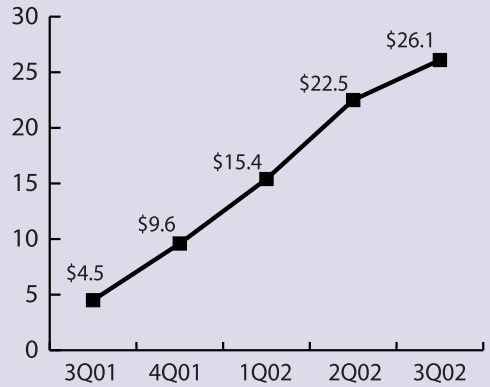
Biosite developed the Triage BNP test under a semi-exclusive license (worldwide, except Japan) to technology and patents developed by Scios Inc. (Sunnyvale, CA). Scios is a biopharmaceutical company whose flagship product is Natrecor (nesiritide), an intravenous drug treatment that helps open arteries and veins in patients with severe CHF. Natrecor was approved by FDA in August 2001. Scios generated $14.1 million from its sales in 2001. Currently, sales are running at more than $100 million per year, based on annualized results for the three months ended Sept. 30, 2002. U.S. sales of Natrecor could ultimately reach $500-$600 million per year, Scios estimates.

Biosite generated approximately $3.4 million from sales of its Triage BNP Test in 2001, and sales are presently running at nearly $40 million per year, based on annualized results for the three months ended Sept. 30, 2002. The test currently accounts for roughly 34% of Biosite's overall annualized sales of $116 million.

Although Biosite's kit is the only FDA-approved BNP test on the market today, Abbott Laboratories and Bayer Diagnostics have diagnostic rights to the BNP protein, and competition from these companies is on its way. In addition, Roche Diagnostics has developed a test using a related protein.

BNP tests being developed by each of these companies run on traditional immunoassay analyzers and could potentially be priced at a steep discount to the current $25 average price tag for Biosite's Triage BNP. The companies were unwilling to discuss their pricing plans, but *DTTR* estimates that BNP prices from these three large IVD companies are likely to range between $15-$20 per test.

**Scios' Revenue From Natrecor** *($MM)*




Source: Scios Inc.

Moreover, Abbott, Bayer and Roche together have immunoassay instruments placed at more than one-third of the nation's hospitals. As a result, these large IVD vendors will be able to simply add their BNP tests to existing test menus.

Still more competition could come from Beckman Coulter, Dade Behring or Diagnostic Products, should they decide to license a BNP test or develop their own.

Here's an update on progress that Roche, Bayer and Abbott are making toward bringing a BNP test to market in the U.S.

**Roche Diagnostics** filed a 510(k) application with FDA for its Elecsys proBNP test in July 2002. Michael Leuther, PhD, manager of Elecsys product marketing, tells *DTTR* that the test should be cleared for marketing within a matter of weeks. Roche has placed Elecsys instruments in 600 customer locations in the U.S., and initial marketing of proBNP will be focused on these sites, he says. The test has been sold in Europe since late 2001.

The Elecsys proBNP test measures an inactive fragment of the BNP hormone, while the Biosite test measures an active fragment. According to Leuther, one benefit of measuring the inactive fragment is that it is more stable and has a higher half-life (90 minutes) than the active fragment (20 minutes). As a result, proBNP circulates in the blood at a higher concentration, making it easier and more reliable to measure, he says.

**Competitive Landscape For BNP Testing**

| *Company* | *Expected BNP Test Market Launch* |
|---|---|
| Biosite | Dec. 2000 |
| Roche Diagnostics | 1st Qtr 2003 |
| Bayer Diagnostics | 2nd Qtr 2003 |
| Abbott Diagnostics | 3rd Qtr 2003 |

Source: *DTTR* from companies

One big benefit of testing for BNP using an automated instrument vs. a point-of-care device is the ability to capture test data in a laboratory information system. Leuther says hospitals are generally wary of using point-of-care devices and have been clamoring for a BNP test that can be run on a traditional analyzer in a central lab. He believes that while there may be a place for point-of-care BNP testing in the outpatient market, inpatient testing will quickly convert to reagent kits from the major IVD vendors as they come to market. Roche is considering a point-of-care test for proBNP, he notes, but hasn't started product development in this area yet.

Leuther estimates that within the next five years, the U.S. market for BNP testing could reach upwards of 40 million tests annually. Assuming that test prices move down to the $10 range from the $20-$25 that Biosite currently charges, this would indicate a market size of $400 million. In terms of the European market, Leuther is not as optimistic. He says demand there has not been very high.

**Bayer Diagnostics** (Tarrytown, NY) plans to file an application with FDA for its BNP test by year's end and have it on the market by the middle of next year, according to a company spokesman. Bayer has developed its BNP test for use on its automated Advia Centaur Immunoassay System, based on a licensing agreement with Shionogi & Co. Ltd. (Osaka, Japan) that was announced in June 2001. Shionogi has marketed its Shionoria BNP test in Japan since 1994 and in Europe since 1997.

**Abbott Diagnostics** (Abbott Park, IL) has an agreement to distribute a BNP test being developed by Axis-Shield (Oslo, Norway). The test is being developed for use on Abbott's AxSym automated immunoassay system and will be exclusively marketed and distributed by Abbott worldwide, except in Japan. The test is expected to be on the market in the U.S. in the second half of 2003, according to Abbott spokesman Don Braakman.

# Igen Says Out-Of-Court Settlement With Roche Near At Hand

Recent statements from the head of Igen International (Gaithersburg, MD) point to progress toward an out-of-court settlement with Roche Diagnostics (Basel, Switzerland) in a licensing dispute over Igen's "Origen" technology for immunoassays. The final outcome could lead to a major shakeup in the $5 billion worldwide market for immunodiagnostics.

Earlier this year, a Maryland district court judge confirmed a jury's verdict that Roche had breached its licensing agreement and ordered it to pay Igen $105 million in compensatory damages, plus $400 million in punitive damages. The ruling also gave Igen the right to terminate its licensing agreement with Roche at any time and gave Igen rights to any improved features Roche has made to the Origen technology. Roche appealed the decision, and a ruling from the U.S. Court of Appeals for the Fourth Circuit is expected within a year, unless an out-of-court settlement is reached first.

In a conference call with analysts on Oct. 29, Sam Wohlstadter, chairman and CEO of Igen, said Roche and Igen were "on a path that should lead to a successful near-term resolution ... We're talking with Roche on a daily basis…This is the first time in a long time that there has been an element of trust between the two sides."

Wohlstadter indicated that terms of the deal will probably involve Roche making a paid-up licensing fee to Igen in return for a non-exclusive license to the Origen technology, which is an integral part of Roche's Elecsys immunoassay product line. "Given the difficulty Roche has had in the past in providing reports and our difficulty in interpreting them, it's best for both sides that there isn't an issue of ongoing royalties," Wohlstadter told analysts. Igen currently gets a licensing fee of 8%-9% on all revenue Roche generates from sales of immunoassay equipment and supplies that utilize the Origen technology.

Wohlstadter also said Igen continues to have discussions with other IVD manufacturers and other companies regarding licensing of Igen's immunoassay technology. He noted that talks could result in some new entrants into this market.

Dennis Roth, analyst at Chesapeake Securities (Baltimore, MD), tells *DTTR* that Roche may need to pay Igen a total of $1 billion or more to reach an out-of-court settlement, including $505 million for damages (as already determined by jury verdict), plus another $500+ million for a non-exclusive paid-up licensing fee for the Origen technology.

John Putnam, analyst at Belmont Harbor Capital (Chicago, IL), concurs that $500+ million is not an unreasonable estimate of the amount Roche may end up paying Igen for a paid-up licensing fee. He estimates that Roche's immunoassay business is currently generating $400 million in revenue annually and is growing by better than 10% per year with a pretax margin of roughly 30%.

Regardless of any potential out-of-court settlement, Putnam believes Igen is likely to license its Origen technology to another IVD company. This technology is probably the largest advance made in immunodiagnostics in the past 10 years, he says,

and he believes companies like Abbott, Beckman Coulter or Diagnostic Products might want to gain access to it.

Meanwhile, Christiane Koesling, head of international media for Roche Diagnostics, would only confirm to *DTTR* that Roche and Igen are in negotiations. "But we agreed with Igen to keep any settlement discussions confidential and believe we are currently still apart from an agreement."

## Bio-Rad Gets Clearance For Rapid CWD Test

Bio-Rad Laboratories (Hercules, CA) has received a veterinary biological permit from the U.S. Department of Agriculture for its rapid test to detect chronic wasting disease (CWD) in deer and elk. Bio-Rad's test is the first commercial CWD kit to be approved by USDA.

As part of the validation process, the test was used successfully in Colorado to provide wildlife managers and hunters with fast results. Norman Schwartz, vice president of life science at Bio-Rad, estimates that the company could sell up to 50,000 CWD tests in Colorado this hunting season. There is also the potential to sell the test in other states where cases of CWD have been detected, as well as in Canada, he notes.

Chronic wasting disease is closely related to "mad cow" disease and its human equivalent, Creutzfeldt-Jakob disease. These diseases eat away at the brain and nervous system and are always fatal. So far, deer and/or elk in 11 Midwestern and Rocky Mountain states—Colorado, Wyoming, Nebraska, South Dakota, Montana, New Mexico, Kansas, Oklahoma, Wisconsin, Minnesota and Illinois—as well as in Canada have been found to be CWD-infected.

HHS Secretary Tommy Thompson recently announced that the U.S. Food & Drug Administration will commission two studies to assess the human health risk of CWD as part of a comprehensive effort to combat its spread in deer and elk herds across the country.

Overall, HHS has proposed spending more than $29.2 million in fiscal 2003 to expand research efforts to fight the growing threat of brain-wasting diseases, including CWD among the nation's deer and elk populations.

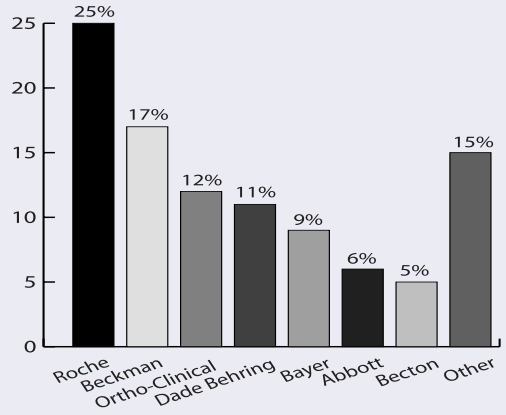
"We must determine whether CWD is a threat to our food supply and how best to stop [its] spread in our deer and elk herds," Thompson said in a statement. "We will aggressively pursue innovative methods to expand research and direct assistance to states to fight the spread of CWD."

Meanwhile, Bio-Rad says its life sciences division has expanded so rapidly in recent years that it is building a new 140,000 square-foot facility at its Hercules campus to house this growing business. The life sciences division includes revenue from the company's "mad cow" and CWD tests as well as sales of instruments and supplies for proteomic and genomic testing. In the three months ended Sept. 30, 2002, revenue at the life sciences division reached $106 million, up 28% over the same period last year, Bio-Rad reported.

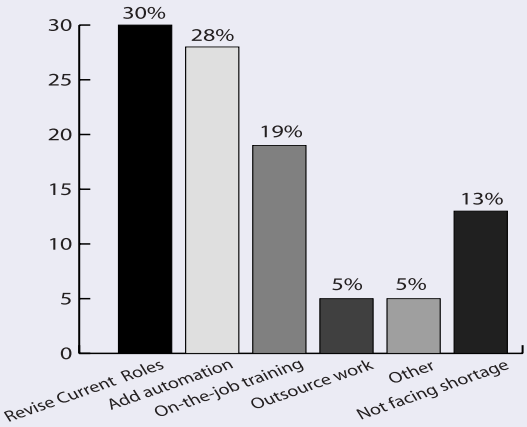
# Roche Has Best Service, According To Lab Institute Survey

In a telephone call-in survey conducted at the 20th annual Lab Institute, sponsored by Washington G-2 Reports on Oct. 23-26 in Arlington, VA, 25% of laboratory managers and administrators selected Roche Diagnostics as the IVD vendor that provides the best level of overall service. Of the 190 participants in the survey, 130 were from hospital labs, 48 from independent labs and 12 from physician office or other lab sites.

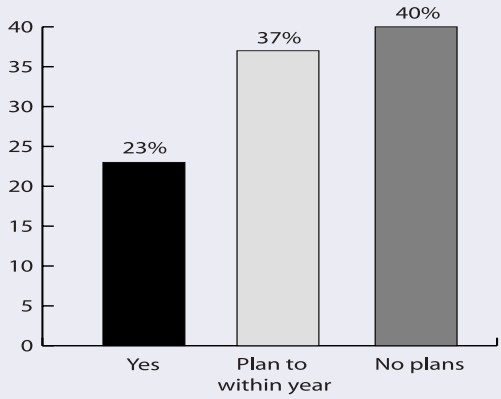
**Which IVD vendor provides the best level of overall service?**




**What best describes the way your lab is coping with the workforce shortage?**




**Does your lab have a front-end or pre-analytical automation system?**




Source: Lab Institute 2002 survey, n=190

Beckman Coulter came in second for best overall service in the survey, with 17% of participants choosing it. Next was Ortho-Clinical Diagnostics, which got 12%, followed by Dade Behring with 11% and Bayer Diagnostics with 9%.

In terms of efforts to cope with the workforce shortage, 30% of survey participants said they were revising current lab worker roles, 28% were adding automation, 19% were focused on providing on-the-job training and 5% were outsourcing more work. Only 13% said their lab was not facing a workforce shortage.

Twenty-three percent of survey participants said their lab currently has a front-end automation system installed and another 37% plan to install one within the next year. Forty percent said their lab has no current plans for automation.

Anecdotally, Taylor McKeeman, director of central lab operations at Spectrum Laboratory Network (Greensboro, NC), tells *DTTR* that his lab recently chose to install an Olympus automation system at its core lab. McKeeman says the workforce shortage, combined with increased testing volume due to consolidation of hospital lab testing and growth in outreach testing, were the key factors in his decision to automate. Spectrum is a consolidated lab venture that provides inpatient testing services to six hospitals in North Carolina and operates a statewide lab outreach testing program.

Michael Huppenthal, manager of pre- and post-analytical services at Johns Hopkins Hospital (Baltimore, MD), says his lab recently installed an Abbott Tecan FE 500. Reasons he cites for its selection: reasonable maintenance plan costs, small space requirements and an easy interface with the lab information system.

# IVD Stocks Up 4% In Latest Four Weeks

*Roche non-voting equity shares, which trade on the Zurich stock exchange, are down 13% to 103 Swiss francs year-to-date. Shares of Bayer, which trade on the German stock exchanges, are down 47% at 18.99 euros per share year-to-date*

The 21 stocks in the G-2 Diagnostic Stock Index were up an unweighted average of 4% in the four weeks ended Nov. 1, 2002, with 15 stocks rising in price and six falling. Year-to-date, the G-2 Index has fallen 32%, compared with a 22% decline for the S&P 500 and a 30% drop for the Nasdaq.

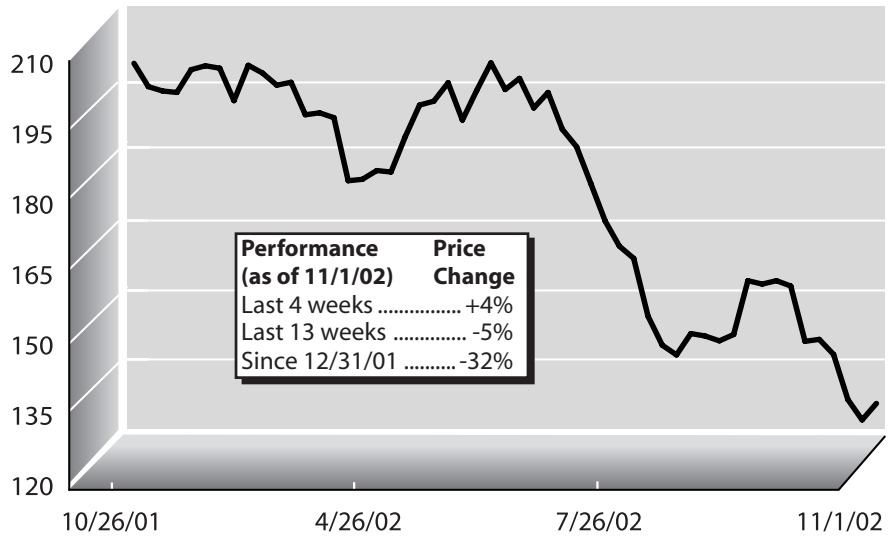
**i-Stat** (East Windsor, NJ) jumped 60% to $3.75 per share for a market capitalization of $75 million. The company recently announced that sales of its test cartridges increased 23% in the third quarter ended last Sept. 30, to 3.2 million units vs. 2.6 million in the same period last year. Meanwhile, i-Stat reported a net loss for the third quarter of $56 million vs. a net loss of $5.2 million in the same period last year; revenue was up 2% to $14.8 million. The $56 million net loss included a write-off of $52 million associated with i-Stat's decision to terminate its distribution agreement with Abbott, effective Jan. 1, 2004 (*DTTR, Sept. 02, p. 10*).

**Igen International** (Gaithersburg, MD) was up 23% to $36.49 per share for a market cap of $865 million. During an Oct. 29 conference call, company chairman and CEO Sam Wohlstadter said Igen is nearing an out-of-court settlement with Roche Diagnostics in a licensing dispute over Igen's "Origen" technology for immunoassays (*see p. 8, this issue*).

Of the latest two IVD companies to begin trading in the U.S. stock market, but not yet part of the G-2 Diagnostic Stock Index, **Dade Behring** (Deerfield, IL) slipped 9% to $15 per share in the four weeks ended Nov. 1 for a market cap of $708 million; **Gen-Probe** (San Diego, CA) jumped 33% to $19.65 per share for a market cap of $472 million.

Meanwhile, shares of **Careside** (Culver City, CA) ceased trading on the American Stock Exchange after the company filed for Chapter 11 bankruptcy reorganization on Oct. 18 (*DTTR, Nov. 02, p. 4*). Careside is now seeking bankruptcy court approval for a $2 million loan from Palm Finance Corp. so it can maintain operations.

## 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.

**Avg. % Price Change, 4 weeks ended 11/1/02**

| UP | Price ($) | % Chg |
|---|---|---|
| Abbott Labs | 41.73 | +1 |
| Becton Dickinson | 30.35 | +4 |
| Bio-Rad | 44.20 | +15 |
| Biosite | 30.74 | +11 |
| Cygnus | 1.23 | +4 |
| Cytyc | 10.91 | +10 |
| Digene | 8.33 | +5 |
| Igen | 36.49 | +23 |
| Inverness Medical | 10.19 | +13 |
| i-Stat | 3.75 | +60 |
| Immucor | 22.28 | +20 |
| Johnson & Johnson | 58.59 | +3 |
| Quidel | 3.02 | +32 |
| TheraSense | 5.96 | +16 |
| Ventana | 17.98 | +12 |
| **DOWN** | | |
| Beckman Coulter | 28.00 | -24 |
| Careside | 0.00 | -100 |
| Cholestech | 5.91 | -5 |
| Diagnostic Products | 42.83 | -6 |
| Diametrics | 2.05 | -4 |
| Meridian | 6.11 | -2 |

# G-2 Insider

*Overwhelming political support suggests that OraSure's rapid HIV-1 test will gain CLIA waived status. CEO Michael Gausling says the company has begun working toward that end*

**Push is on for rapid HIV-1 test waiver:** Now that OraSure has received FDA clearance to market its rapid HIV-1 test for use at labs certified to do moderately complex testing under CLIA (Clinical Laboratory Improvement Amendments), the company is being pushed by a wide number of public health officials, health organizations and HIV/AIDS groups to seek a CLIA waiver for the test (*p. 3, this issue*). The waived test category is the least regulated under CLIA, and the main requirement is that a waived test be performed according to the manufacturer's instructions.

In a controversial statement, HHS Secretary Tommy Thompson said: "I strongly urge OraSure to apply for a CLIA waiver. Then the test could be given in many more healthcare settings, perhaps even administered by social workers in HIV counseling centers. But the process can't begin until OraSure applies for the waiver, so I ask them to please apply now."

Support for a waiver has come from all sides of the political spectrum. In an Oct. 22 letter to Thompson, the Congressional Black Caucus noted: "Currently, individuals testing for HIV must wait one week to two weeks for their results ... By eliminating the waiting period, rapid testing has a vital role in CDC's goal of reducing the number of HIV infections each year from 40,000 to 20,000 and ensuring that 98% of those infected know their status."

But one influential group has come out against a waiver. At a meeting in Atlanta, GA, on Sept. 11-12, the Clinical Laboratory Improvement Advisory Committee (CLIAC) said it fears that false results would have catastrophic consequences for patients and the public. CLIAC, which is comprised mostly of laboratory directors and pathologists whose labs can be cut out of the loop when tests achieve waived status, advises the government on scientific and technical issues under CLIA.

## Company References

Abbott Labs 847-937-6100
Bayer Diagnostics 914-631-8000
BioMerieux (Durham, NC) 800-654-0331
Bio-Rad Labs 510-724-7000
Biosite 858-455-4808
Dade Behring 847-267-5300
Gen-Probe 858-410-8000
Igen 301-869-9800
i-Stat 609-443-9300
OraSure 503-641-6115
Roche Diagnostics 317-849-9350
Scios 408-616-8200







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