Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

UGT1A1 Test Off To Slow Start, Despite Obvious Benefits

Despite its seemingly obvious clinical utility, Third Wave Technologies' new pharmacogenomic test, Invader UGT1A1, is off to a slow start, according to several labs contacted by *DTTR*. The test has been shown to help predict which patients will respond to Pfizer's highly toxic colorectal cancer drug Camptosar (generically known as irinotecan), which has been on the U.S. market for five years.

The reluctance of oncologists to prescribe the test illustrates just how cautious physicians are to adopt new technologies and to change practice patterns. The market introduction of UGT1A1 testing also provides an example of the lack of marketing support that pharmacogenomic tests are likely to receive from the big drug companies.

The molecular lab at Dartmouth-Hitchcock Medical Center was the first to begin offering the Invader UGT1A1 test, which was cleared by the FDA for sale in kit form in August 2005, for clinical use in the United States. Greg Tsongalis, Ph.D., director of molecular pathology at Dartmouth-Hitchcock, says his lab began marketing the test in the fall of 2005, but demand for the assay has been rather low, approximately three to five tests per week, so far. Dartmouth-Hitchcock is selling the test at a list price of about $300. For more details, see *Inside the Diagnostics Industry*, pp. 5-7.

Gen-Probe Launches DNA Test For Prostate Cancer

Gen-Probe (San Diego, CA) has begun shipping an analyte specific reagent (ASR) version of its PCA3 Aptima test for prostate cancer detection. Clinical trials for the test are underway and Gen-Probe expects to submit an application for premarket approval to the FDA next year. Gen-Probe says that its pre-clinical trials studies on a prototype assay showed sensitivity of 66% and specificity of 75% from urine samples obtained after a digital rectal exam, compared with only 30% specificity of the PSA test in the same population. The test is based on technology licensed from Diagnocure (Quebec City, Canada), which specializes in the development of cancer tests. And Gen-Probe has stated that the test will be a cornerstone in its strategic focus on cancer diagnostics.

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▲ **Gen-Probe Launches DNA Test For Prostate Cancer,** *from page 1*

Clinical studies have shown that the PCA3 gene is overexpressed only in malignant prostate tissue. Diagnocure initially developed a first-generation test for PCA3 called uPM3 that has been offered in the United States for the past two years as a homebrew test by Bostwick Laboratories (Richmond, VA), a privately held lab that specializes in urological diseases. Bostwick will now switch to Gen-Probe's PCA3 Aptima assay, and Gen-Probe has the right to sell the assay's reagents to other labs as well.

The weak specificity of the traditional PSA test leads to unnecessary and expensive biopsies that contradict the result of the PSA in more than two out of three cases.

Patients who receive the PCA3 test undergo a DRE by a urologist. The exam causes cells from the patient's prostate to be shed into the urine, and the urine sample, containing the released cells, is sent to a reference laboratory to be tested for genetic expression of the PCA3 gene. Because PCA3 is specific for prostate cancer cells, it is potentially a much better marker for prostate cancer than PSA, which cannot distinguish between cancer and benign conditions such as BPH and prostatitis.

The PCA3 marker was discovered by researchers at the University Hospital in Nijmegen, Holland, and Diagnocure licensed worldwide patent rights for diagnostic and therapeutic applications in May 2000.

Diagnocure signed its licensing agreement with Gen-Probe in November 2003. Diagnocure received an upfront fee of $3 million from Gen-Probe and has since received another $7.5 million for meeting milestones and helping with clinical studies.

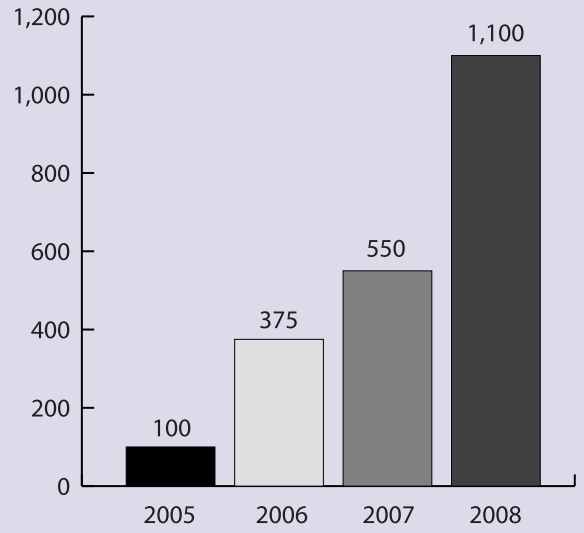
Gen-Probe has exclusive worldwide rights to diagnostic tests based on the PCA3 marker and will pay Diagnocure royalties of 8% on test sales to labs for the first $50 million of sales and 16% thereafter, according to Thom Skinner, chief financial officer for Diagnocure. He says Gen-Probe is selling the ASRs for PCA3 to labs at roughly $100 per assay, which means that Diagnocure will initially earn $8 per test. And 20% of all royalties received by Diagnocure will be remitted to the University of Nijmegen.

Gen-Probe is expected to have a CE-marked PCA3 test on the European market later this year, and an FDA-cleared test kit for the U.S. market should be released in 2008. Labs are expected to price the test at roughly $200 to $300 (after discounts).

Skinner says the assay will initially be used as a tool to help resolve indeterminate prostate cancer cases where a man has an elevated PSA level, followed by a negative biopsy. The PCA3 test could eliminate or reduce the need for a first or second biopsy, which can cost in the range of $1,000 to $2,000 each.

There are an estimated 20 million to 25 million PSA tests performed each year in the United States, of which roughly 4.5 million show elevated levels (>4.0 ng/ml), according to Skinner. About two out of every three elevated PSA tests has a negative biopsy, so the potential U.S. market for PCA3 is about three million tests per year, he says. The U.S. market potential for PCA3 could double if it becomes adopted to resolve indeterminate prostate cancer cases at the 2.5 ng/ml PSA level, he adds.

Estimates for PCA3 Test Volume in United States *(in thousands)*



Source: National Bank Financial

Skinner says the test received a big vote of confidence in June 2005, when GlaxoSmithKline opted to use PCA3 to test up to 6,800 patients enrolled in clinical trials in 37 countries, rather than use the PSA test. The trials are to test GSK's cancer therapy Avodart to see if the drug can reduce the risk of prostate cancer in men at increased risk of the disease.

Under his most conservative estimate, Hugues Bourgeois, an analyst at the Canadian investment bank National Bank Financial, believes the volume of PCA3 tests in the United States could grow from 100,000 tests in 2005 to 1.1 million tests in 2008. This estimate, if achieved, would translate into $110 million of annual revenue for Gen-Probe, $17.6 million for Diagnocure (16% royalty level), and $275 million for the laboratories, assuming average reimbursement of $250 per test.

Bourgeois believes that one of the biggest challenges that PCA3 will face is physicians' resistance to change. Even though new medical products may offer superior performance, professionals are often reluctant to modify their diagnostic and therapeutic procedures, he notes. He says another big challenge will be the cost of PCA3 testing. As previously noted, reference labs are expected to charge between $200 and $300 per PCA3 test versus under $25 for the traditional PSA test.

Sysmex Scores Big Contract With ACL Laboratories

ACL Laboratories (West Allis, WI) says it has chosen to standardize its hematology testing with instrumentation from Sysmex America (Mundelein, IL). Under the three-year agreement (with two optional one-year extensions), ACL will install Sysmex hematology systems at all of its 65 hospitals and labs. Installation began in December and is scheduled for completion in September 2006, according to Jay Schamberg, M.D., general manager for ACL. He says ACL is currently using hematology instruments from a variety of vendors, but mostly from Abbott Labs.

The contract with Sysmex follows ACL's installation of Sysmex's éCLAIR Physician Portal for electronic test ordering and results reporting. Schamberg says ACL went live with results reporting in May 2004 and order entry in August 2005.

Next on the agenda for standardization at ACL is chemistry and immunochemistry. Schamberg says system evaluations are underway.

ACL Laboratories is a for-profit C-corporation that manages the laboratories at Aurora Health Care (Milwaukee) and Advocate Health Care (Chicago). ACL employs 2,020 FTEs that performed 15 million billable tests in 2005, including 35% to 40% from outreach volume.

Von Prondzynski Leaves Roche Diagnostics

Roche Holdings (Basel, Switzerland) says that Heino von Prondzynski, age 55, chief executive of its worldwide diagnostics business, has resigned and been replaced by an internal candidate, Severin Schwan, effective January 1. Von Prondzynski had decided to retire to pursue personal interests, the company said in a statement.

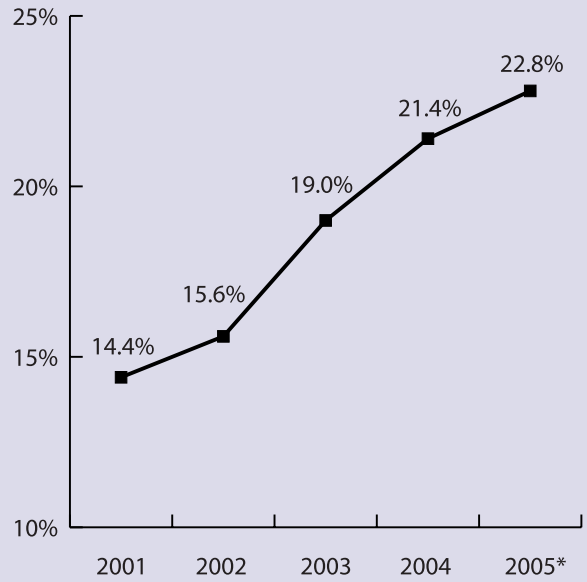
The 38-year-old Schwan began with Roche in 1993 at the corporate finance department in Basel. He then became head of global finance and services for Roche Diagnostics, and he took over as head of the Asia-Pacific region for Roche Diagnostics in 2004.

Von Prondzynki's departure is the third major change at Roche Diagnostics within the past year. In June 2005, Tiffany Olson, 46, became head of North America, and president and chief executive of Roche Diagnostics Corp. (Indianapolis, IN). She replaced Martin Madaus, who resigned to become chief executive of Millipore Corp. (Billerica, MA) in December 2004.

In addition, *DTTR* has learned that Dick Aderman, senior vice president and general manager for centralized and molecular diagnostics in the United States, resigned from Roche in May 2005. Aderman is now president and chief executive of ISPRIT (Carmel, IN), a point-of-care disease management software company founded in 2004.

Roche has split Aderman's previous job into two new positions. In July 2005, Lonnie Shoff, former vice president and general manager of applied science, was promoted to senior vice president, applied science and molecular diagnostics. And Andrew Thomson, former head of global marketing for the centralized diagnostics, was promoted to senior vice president, centralized diagnostics.

Roche Diagnostics: Operating Profit Margins



*For six months ended June 30, 2005 Source: Roche

Finally, late last year, Roche hired Mike Samoszuk, M.D., as chief medical officer for Roche Diagnostics—a new position. Samoszuk, who received his M.D. from Harvard Medical School with a concentration in immunology, was most recently associate professor of pathology and radiology at the University of California, Irvine.

A Roche spokeswoman would only tell *DTTR* that the recent management changes were all done in "the natural course of business." On the other hand, a skeptic might surmise that Roche's executive committee in Switzerland has been disappointed with the financial performance of the diagnostics business, especially in the United States. On a worldwide basis, Roche Diagnostics' profitability has been increasing steadily over the past few years (see graph), but revenue growth has been less impressive (up 4% in the first half of 2005 after adjustments for currency fluctuations).

How Long Will It Take For Oncologists To Embrace UGT1A1 Testing?

Despite the clinical benefits and cost effectiveness of UGT1A1 testing, oncologists have been slow to adopt it into their practice patterns to date.

Gerald Miller, Ph.D., chief of immunology and microbiology at Regional Medical Laboratories (RML-Tulsa, OK), says his lab added the Invader UGT1A1 test to its menu at a list price of $450 in November. However, Miller says RML, a big outreach lab based at St. John's Medical Center, has seen little demand for the test from oncologists so far. "It makes an incredible amount of sense. I can't understand why physicians aren't ordering it, but it's got tremendous potential," he says.

The UGT1A1 test detects variations in the UGT1A1 gene that reduce an individual's ability to metabolize Camptosar. Approximately 10% of the North American population inherits two copies of the gene allele (UGT1A1*28)—one from each parent—and are at a much higher risk of having a toxic reaction to the drug. In addition, patients with one gene allele are at a small risk of having a toxic reaction.

Camptosar labeling was recently updated to include dosing recommendations based on a patient's UGT1A1 status. "A reduction in the starting dose by at least one level of Camptosar should be considered for patients known to be homozygous [having two copies] for the UGT1A1*28 allele," according to the new labeling.

Despite the new labeling, Pfizer, which has marketing rights to Camptosar in the United States, does not seem to be expending much effort on spreading the word to physicians on the benefits of UGT1A1 testing. And for now, it seems that oncologists are sticking with a trial-by-error-type approach to writing prescriptions for Camptosar, observes *DTTR*.

Risk of Toxicity for Camptosar (irinotecan)

Group	*Prevalence*	*Risk of Toxicity*	*Treatment Guide*
All patients	NA	10%	NA
Patients with two copies of UGT1A1*28	10%	50%	Treat with alternative drug or dose
Patients with one copy of UGT1A1*28	40%	12.5%	Treat with alternative drug or dose
Patients win no UGT1A1*28 alleles	50%	0%	Treat with conventional dose

Source: *DTTR* based on data from Innocenti et al (2004) and Lawrence Lesko, Ph.D., presentation to FDA pharmacology subcommittee

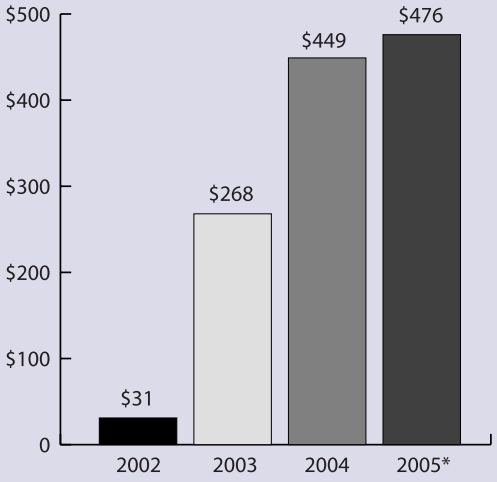
Cost Savings from UGT1A1 Testing

Colorectal cancer is the fourth most commonly diagnosed cancer in the United States., with over 145,000 new cases per year. It accounts for nearly 60,000 deaths per year in the United States.

Assuming that 50,000 colorectal cancer patients received the UGT1A1 test at an average price of $300 would indicate a potential U.S. market for lab testing of $15 million per year. That's a meaningful amount for the lab industry, but it's nothing compared with the estimated $476 million that Pfizer generated from prescription sales of Camptosar in the United States last year.

A $300 UGT1A1 test looks like a downright bargain, considering that a typical eight-week regimen of Camptosar can cost roughly $10,000.

Pfizer's U.S. Revenue from Camptosar ($ millions)



*Revenue for 2005 is estimated based on reported sales for the nine months ended Sept. 30, 2005
Source: Pfizer

The potential savings would not only include a decrease in inappropriate prescriptions or dosing, but also a reduction in the number of adverse reactions, which can include neutropenia, a blood disorder that reduces the body's ability to fight off bacterial infections, and severe diarrhea.

But with no direct financial incentive, it's unlikely that Pfizer will integrate UGT1A1 testing into its marketing program for Camptosar any time soon, observes *DTTR*. Note: *DTTR* called Pfizer's media relations department several times over the course of three days to ask them what the company was doing to promote the use of UGT1A1 testing before Camptosar prescriptions, but we did not receive a response.

Reference Labs Will Need to Educate Oncologists

So it looks like it's up to the national reference labs to spread the word. Third Wave recently announced that Genzyme Genetics (Westborough, MA) would be its preferred laboratory partner for Invader UGT1A1. Third Wave spokesman Rod Hise tells *DTTR* that the contract with Genzyme is non-exclusive. Terms call for Genzyme to get preferential pricing in exchange for launching a physician education and marketing campaign for the UGT1A1 test.

Carole Cuny, oncology product manager for Genzyme Genetics, says Genzyme's 70 reference lab sales reps will work with Third Wave's sales staff to educate physicians about the benefits of UGT1A1 testing through seminars, medical group conferences, and one-on-one consultations. Cuny says Genzyme will perform the test at it main molecular testing lab in Westborough, Massachusetts, at a list price of $750.

Hise says the UGT1A1 test, which was cleared by the FDA for sale in test kit form in August 2005, will continue to be made available to other labs.

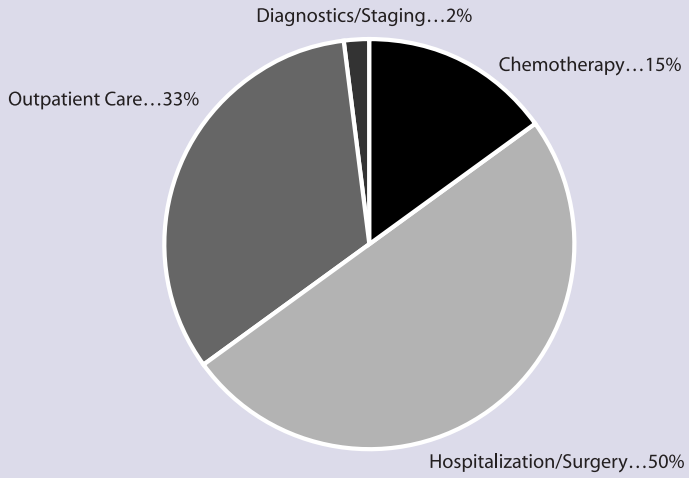
Third Wave licensed the UGT1A1 technology from Mayo Clinic (Rochester, MN), which acquired exclusive rights to the technology from the University of Chicago. Mayo Clinic's reference laboratory, Mayo Medical Laboratories, began offering a homebrew-version of the UGT1A1 test in December at a list price of $680. Mayo says it plans to sublicense the UGT1A1 technology to other

Reference Labs Marketing UGT1A1 Testing

Laboratory	*Technology*	*List Price*	*Introduction Date*
Dartmouth-Hitchcock	Third Wave	$300	September 2005
Genzyme Genetics	Third Wave	750	December 2005
Massachusetts General	Third Wave	NA	NA
Mayo Medical Laboratories	homebrew	680	December 2005
Regional Medical Laboratories	Third Wave	450	November 2005

Source: *DTTR* from laboratories

Estimated Distribution of Per-Patient Lifetime Costs of Colon Cancer*



*includes all stages
Source: *DTTR* based on national health expenditure data from CMS and article in the fall 2003 issue of *Chronic Diseases in Canada*, titled "Lifetime Costs of Colon and Rectal Cancer Management"

academic medical centers, laboratories, IVD companies, and drug makers. Mayo spokesman Lee Aase tells *DTTR* that interest in the UGT1A1 test has been high, although he would not disclose any specific test volumes. Aase says Pfizer is not involved with any of the marketing that Mayo is doing for the test.

"This test helps physicians prescribe the right drug at the right dosage for their patients," says Dennis O'Kane, Ph.D., the Mayo Clinic scientist who led Mayo's development of its screening test. "Patients susceptible to side effects may be able to take the drug, but at a much lower dose. At a minimum, it will alert physicians which patients need to be watched extremely closely for signs of life-threatening side effects," he notes.

A Quicker Route to Encouraging the Use of Pharmacogenomics

Educating physicians and getting them to change their practice patterns is likely to take time. A quicker route may be for laboratories and test developers to go straight to the payers: Medicare, Medicaid, managed care, etc. Obviously payers have a financial incentive to optimize drug therapies and reduce adverse reactions. To encourage the use of a test like UGT1A1, payers could make it a requirement before they reimbursed for drug treatments.

Despite the current general lack of cooperation between drug companies and the pharmacogenomic test developers, some industry experts predict the two groups will soon begin coming together. In fact, Stephen Little, Ph.D., chief executive of DxS Ltd. (Manchester, England), which provides genotyping services for new drug development, sees the day when drug companies and test developers form alliances to co-develop and market new drugs with companion diagnostics. This scenario could greatly increase the value of test kits and lab services in the reimbursement equation (*see table below*).

Pharmaceutical & Diagnostic Alliance Scenarios

Independent: Companies follow their own strategy for making Dx and Rx available, but share details of development timing and plans. Diagnostic company gets 10% of combined revenue/drug company gets 90%.

Co-Development Partnership: Pharmacogenomic requirement identified during drug development and diagnostic company contracted to make test available in the market. Options are to follow a traditional Dx sales maximization strategy or focus on getting the most value out of the Rx/Dx combination and share revenue on a prearranged basis. Dx gets 16%/Rx gets 84% of combined sales.

Product Rescue: As with co-development, but with greater urgency and, potentially, Dx company intellectual property. Dx gets 21%/Rx gets 79%.

Source: Stephen Little/DxS Ltd.

DNA Blood Test For Colorectal Cancer Moves Closer To Market

The first DNA-based blood test for colorectal cancer could be on the U.S. market within a year or two. Epigenomics AG (Berlin, Germany) says that three separate clinical studies on more than 2,000 blood samples showed its test can detect an altered gene associated with colorectal cancer from 50% to 65% of the time, in both early and advanced cancer.

The test is based on Epigenomics' DNA-methylation technology. DNA methylation is a natural "switch" that controls gene expression, giving rise to distinct patterns in cells, including those found in cancer and other diseases. Based on these methylation patterns, Epigenomics says cancer can be detected and classified from tissue, blood, or urine samples.

Roche Diagnostics has a worldwide exclusive license to commercialize the testing technology and plans to begin adapting the marker for its PCR platforms in 2006. The test could be used as a screening tool for colorectal cancer in men and women over age 50, according to Gary Schweikhardt, president of Epigenomics' Seattle unit, which developed the test. In a recent article in the *Seattle Times*, Schweikhardt said he thinks the test could sell for $100 or less.

The collaboration between Roche and Epigenomics began in March 2003, when they signed a three-year agreement to develop a range of molecular diagnostics and pharmacogenomic cancer tests, with a focus on colorectal, prostate, and breast cancer.

The agreement has been extended into a fourth year. Epigenomics is responsible for marker discovery, identification, and pre-validation. Diagnostic test development, clinical trials, product manufacturing, regulatory submissions, and all sales and marketing worldwide will be handled by Roche. In addition to an upfront payment of 4 million euros (US $4.3 million), Roche is providing R&D funding, milestone payments, and royalties on product sales to Epigenomics.

While Roche has decided to move forward with commercialization of a DNA-methylation test for colon cancer, it also recently chose to discontinue work on development of a prostate cancer staging test using Epigenomics' technology.

Biosite Submits 501(k) For MPO Tests

Biosite licensed certain diagnostic rights to MPO in 2004 under an agreement with the Cleveland Clinic Foundation and Prognostix, Inc. (see DTTR, March 2004, pp. 1-2).

Biosite(San Diego, CA) has submitted a 510(k) Premarket Notification with the FDA for diagnostic tests for myeloperoxidase (MPO), a biomarker of inflammation in the walls of coronary arteries. MPO is believed to be useful as an aid in the early diagnosis of myocardial infarction and could signal risk for heart disease or heart attack in patients with chest pain or acute coronary syndromes (ACS).

Biosite plans to offer a single Triage MPO Test and a second generation Triage Cardio Profiler Panel that will include MPO. The panel currently measures the levels of troponin and its complexes, along with CK-MB, BNP, and myoglobin in blood, and is used as an aid in the diagnosis of heart attack, diagnosis and assessment of severity of congestive heart failure, and risk stratification of patients with ACS.

Accuracy Questions Likely To Delay OTC HIV Test

Over the past several weeks at least a half dozen big-city health agencies in New York, Los Angeles, and San Francisco have stopped using OraSure Technology's OraQuick oral fluid HIV test because of a spike in false positives. For example, officials of the San Francisco Department of Health have reported that in the last three months of 2005, they recorded a rate of eight false positives per 1,000 tests, or twice the usual rate of four per 1,000.

The OraQuick test received a CLIA waiver for testing on oral fluid samples in March 2004, and OraSure is now seeking FDA approval to sell the test over-the-counter at grocery and drug stores. Questions about the accuracy of the test, whether valid or not, are likely to delay a decision by the FDA.

At an investor conference in New York City on January 10, Douglas Michels, chief executive of OraSure, said the company had found no correlation between the false positive reports and particular lots of the OraQuick test. This suggests that a site-specific factor, such as user error, could be behind the uptick in false positives at some locations, he said.

Michels said that the test has been 99.8% accurate in identifying people who do not have HIV, according to a review of 112,000 tests in eight states last year, including those that have reported a spike in false positives. This matches the test's label claims, he said.

JAMA Study Identifies New Gene-Based Test For LQTS

Italian researchers have developed a new gene-based test for long QT syndrome (LQTS), according to a study published in the December 21 issue of the *Journal of the American Medical Association (JAMA).*

LQTS is an inherited disease that predisposes a person to increased risk for sudden death or heart rhythm irregularities. People with this condition are known to have a genetic mutation called LQTS mutation. This group is likely to go undiagnosed with available testing methods. If untreated, they have a 10% chance of a major heart complication by age 40.

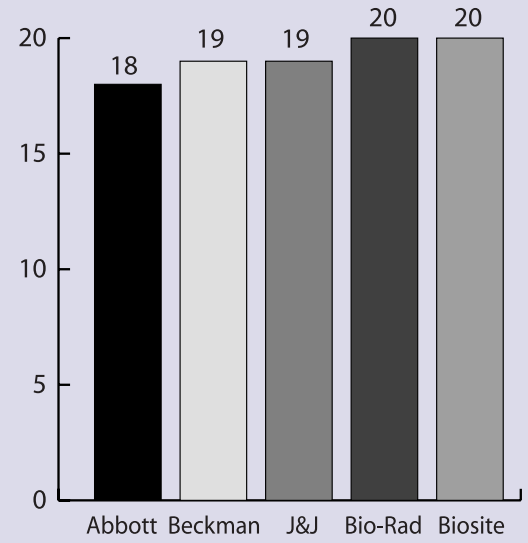
The researchers, led by Carlo Napolitano, M.D., Ph.D., of the S. Maugeri Foundation, Pavia, Italy, conducted genetic testing on 430 LQTS patients and 1,115 of their family members, looking for mutations linked to the disorder. They identified 235 different mutations—including 138 new ones—in 310, or 72%, of the 430 patients.

"We have developed an approach to improve the efficiency of genetic screening for LQTS," the researchers wrote. The new method "may facilitate the access to genetic testing to a broader group of individuals, such as patients receiving drugs that prolong LQTS interval; family members of individuals with idiopathic ventricular fibrillation; and depending on results of further investigation, members of the general population to define the prevalence of known genetic variants of LQTS," according to the researchers.

IVD Stocks Rose 12% In 2005 Led By IRIS, Quidel, Meridian

Thirty-one IVD stocks climbed an unweighted average of 12% last year versus respective gains of 3% and 1% for the S&P 500 Index and the Nasdaq. The NYSE Healthcare Index was up 5.5% in 2005. Overall, 19 IVD stocks rose in price and 12 fell.

Price-to-Earnings: Least-Expensive IVD Stocks



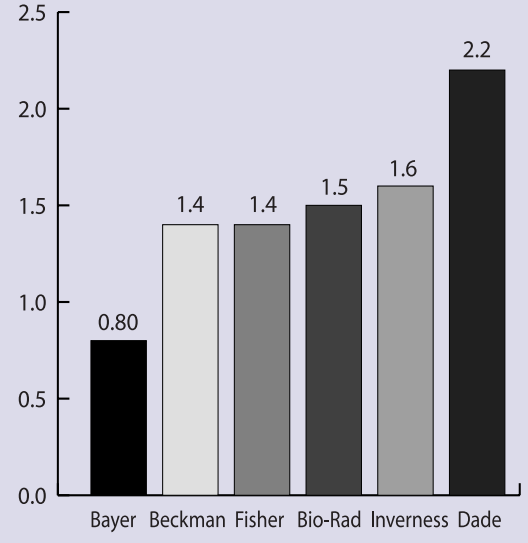
Source: *DTTR*

IRIS International (Chatsworth, CA), which makes automated urinalysis systems, was the best-performing IVD stock in 2005 with a gain of 124% to $21.86 per share. For the nine months ended Sept. 30, 2005, the company reported net income of $4.4 million, or $0.25 per share, versus $1.4 million, or $0.09 per share; revenue increased by 45% to $45.5 million driven by strong sales of its iQ200 Automated Microscopy Analyzer.

Quidel Corp. (San Diego, CA), which had been the worst-performing IVD stock in 2004, rebounded 112% to $10.76 per share in 2005. Quidel's stock price gains included a surge in late December after it received an okay from the FDA to market its rapid QuickVue Influenza A + B test as having 94% sensitivity for detecting the two flu-virus subtypes using nasal-swab specimens. The test's previously approved claim was for 72% sensitivity. In addition, the FDA is allowing Quidel to include study data in package inserts that shows its QuickVue test can detect cultured avian-influenza viruses, including subtype H5N1. The test's capability in detecting H5N1 in patients has not been established.

Meridian Bioscience (Cincinnati, OH) was up 76% to $20.14 per share. For the year ended Sept. 30, 2005, Meridian reported that its net income rose 37% to $12.6 million, or $0.52 per share, from $9.19 million, or $0.40 per share; revenue was up 17% to $93 million. Meridian said growth was driven by the launch of its new product, ImmunoCard C. difficile Toxins A & B. The company projects fiscal 2006 earnings of $0.60 to $0.63 per share on revenue of $103 million to $107 million.

Price-to-Sales: Least-Expensive IVD Stocks



Source: *DTTR*

The worst-performing IVD stock in 2005 was **Third Wave Technologies** (Madison, WI), which declined 65% to $2.98 per share. Third Wave had been one of the best performers in 2004 when it rose by 69%. The company recently announced that its chief executive and president, John Puisis, has resigned and will be replaced by Kevin Conroy, 40, who was the company's vice president and general counsel. Third Wave's stock suffered in 2005 as its clinical diagnostics business posted sluggish growth.

At year-end 2005, the least expensive IVD stock based on its price-to-earnings ratio was **Abbott Laboratories**, with a P/E of 18, followed by **Johnson & Johnson** and **Beckman Coulter**, each with a P/E of 19.

In terms of price-to-sales, **Bayer Group** is the cheapest, trading at 0.80 times its annual revenue. Distributor **Fisher Scientific** and **Beckman Coulter** each trade at 1.4 times their annual revenue, followed by **Bio-Rad Labs**, 1.5x; **Inverness Medical**, 1.6x; and **Dade Behring**, 2.2x. The most expensive IVD stocks by price-to-sales are: **Immunicon**, 21.6x; **Exact Sciences**, 13.6x; **Luminex**, 9.4x; and **Gen-Probe**, 8.6x.

IVD Stock Review for 2005

Company (ticker)	Price 12/31/04	Price 12/31/05	52-Week % Chg	P/E Ratio	Div. Yield	Market Capitalization
IRIS International (IRIS)	$9.75	$21.86	124%	74	N/A	$354M
Quidel (QDEL)	5.08	10.76	112	NA	N/A	354M
Meridian (VIVO)	11.42	20.14	76	39	1.5%	525M
Dade Behring (DADE)	27.93	40.89	46	33	0.2	3.61B
Stratagene (STGN)	7.57	10.09	33	30	2.3	223M
Ventana (VMSI)	32.00	42.35	32	66	N/A	1.53B
OraSure (OSUR)	6.72	8.82	31	59	N/A	402M
Luminex (LMNX)	8.88	11.62	31	N/A	N/A	370M
Affymetrix (AFFX)	36.55	47.75	31	53	N/A	3.18B
Bayer (BAY)	33.98	41.76	23	37	1.3	30.51B
Cholestech (CTEC)	8.20	9.92	21	22	N/A	147M
Bio-Rad Labs (BIO)	57.37	65.44	14	20	N/A	1.71B
Abaxis (ABAX)	14.49	16.48	14	66	N/A	330M
Digene (DIGE)	26.15	29.17	12	NA	N/A	646M
Gen-Probe (GPRO)	45.21	48.79	8	46	N/A	2.48B
Qiagen (QGEN)	10.95	11.73	7	29	N/A	1.73B
HemoSense (HEM)	5.50	5.86	7	N/A	N/A	57M
Becton Dickinson (BDX)	56.80	60.08	6	22	1.4	14.88B
Cytyc (CYTC)	27.57	28.23	2	32	N/A	3.22B
Immucor (BLUD)	23.51	23.36	-1	41	N/A	1.06B
Fisher Scientific (FSH)	62.38	61.86	-1	24	N/A	7.59B
Johnson & Johnson (JNJ)	63.42	60.10	-5	19	2.1	178.79B
Inverness Medical (IMA)	25.10	23.71	-6	NA	N/A	649M
Biosite (BSTE)	61.54	56.29	-9	20	N/A	981M
Diagnostic Products (DP)	55.05	48.55	-12	22	0.5	1.43B
Beckman Coulter (BEC)	66.99	56.90	-15	19	0.9	3.54B
Abbott Labs (ABT)	46.65	39.43	-15	18	2.7	61.16B
TriPath Imaging (TPTH)	8.97	6.04	-33	N/A	N/A	231M
Exact Sciences (EXAS)	3.83	2.21	-42	N/A	N/A	58M
Immunicon (IMMC)	6.98	3.43	-51	N/A	N/A	94M
Third Wave (TWTI)	8.60	2.98	-65	N/A	N/A	123M
Unweighted Avg.			12			

N/A=not applicable because the company has reported a loss in the most recent four quarters. Source: *DTTR*

G-2 Insider

Screening men with a PSA test does not improve survival rates, according to a study published in the January 9 issue of the medical journal *Archives of Internal Medicine*. Researchers at the Yale School of Medicine and the Veterans Affairs Connecticut Healthcare System reviewed the medical records at 10 Veterans Affairs medical centers of 1,002 men ages 50 and older—half of whom had died of prostate cancer.

They found no difference in the survival rates for those men that had been given a PSA test and those who had not. In addition, they found that combining a PSA test with a digital rectal exam produced even worse results.

"Based on available evidence, including the present study, recommendations regarding screening for prostate cancer should not endorse routine testing of asymptomatic men to reduce mortality," concluded lead researcher John Concato, M.D. "Rather, the uncertainty of screening should be explained to patients in a process of 'verbal informed consent,' promoting informed decision making," he said.

However, an editorial accompanying the study's findings noted that 78% of male primary care physicians and 95% of urologists over 50 have themselves had at least one PSA screening, so they apparently have decided that the test is useful.

Prostate cancer strikes more than 230,000 U.S. men a year, and more than 30,000 die of it. The limitations of PSA testing have been known for years, and this study suggests the need to develop more accurate means of detecting prostate cancer (*see related article in this issue, pp. 1-3*).

Company References

ACL Laboratories
800-877-7016

Biosite 858-455-4808

Diagnocure 418-527-6100

Epigenomics
206-883-2900

Gen-Probe 858-410-8000

IRIS Intl. 818-709-1244

OraSure 610-882-1820

Pfizer 212-573-2323

Quidel Corp.
858-552-1100

Roche Diagnostics
317-521-2000

Third Wave 888-898-2357

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