Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

G-2/PSA Molecular Diagnostics Conference Highlights

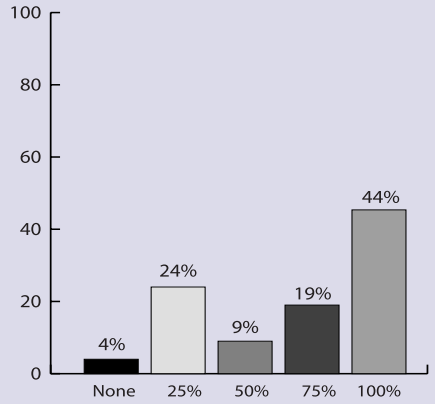
Most pathology groups are missing the boat when it comes to molecular diagnostics, Tricia Hughey, chief executive of UniPath (Denver, CO), told an audience of some 250 pathologists, lab owners, and executives at a January 26 to 27 conference in Miami titled *Building a Molecular Diagnostics Laboratory*, presented by Washington G-2 Reports and Pathology Service Associates (PSA).

Citing a July 2005 survey by PSA, Hughey noted that almost half of pathology groups are performing no molecular procedures and less than 5% are performing all of their own molecular tests (*see graph*). She added that molecular testing had the highest profit margin and was growing three times faster than routine cytology and anatomic pathology procedures at UniPath, which employs 26 pathologists and operates an independent lab in Denver, Colorado.

The two-day conference featured 15 presentations. Among the takeaway messages were: 1) test volumes for molecular diagnostics are growing well into the double digits on an annual percentage basis; 2) the greatest growth is likely to occur in molecular diagnostics for cancer; 3) clinical relevance and physician education are the key drivers of test adoption; and 4) the consultative services that local pathologists can provide are highly valued by physicians.

For more conference details, see *Inside The Diagnostics Industry*, pp.5-7.

What percentage of molecular diagnostic testing do you refer outside your laboratory?



Source: PSA, n=75 pathology groups

(More survey results on page 12)

Merck CEO Repeats Interest In Diagnostics

To drive growth, Merck plans to "pursue certain acquisitions in diagnostics and devices—not to build a standalone business in that area—but rather to enhance our core business," Richard Clark, chief executive of Merck (Whitehouse Station, NJ) told analysts and investors at a special meeting at the company's headquarters on December 15. Clark said Merck was now focused on nine priority disease areas: Alzheimer's disease, atherosclerosis, cardiovascular disease, diabetes, novel vaccines, obesity, targeted therapies in cancer, pain, and sleep disorders.

➥ *p. 2*

▲ **Merck CEO Repeats Interest In Diagnostics,** *from page 1*

DTTR *believes that Merck's experience with Vioxx has been a major factor in its decision to get into diagnostics and pharmacogenomics.*

In a reference to the promise of pharmacogenomics, Clark said, "We are committed to developing products that are highly valued by patients, physicians, and payers alike. They will value them because of what they will provide—targeted, differentiated best-in-class treatment. And we will support these products through their lifecycle, constantly looking for continuous improvement in their indications and use."

"We must integrate key product enablers, such as biomarkers, to differentiate Merck's medicines in the marketplace," he added. Clark initially revealed his interest in the diagnostics area at a meeting with Wall Street analysts in late October (*see DTTR, December 2005, pp. 1-2*).

DTTR believes that one reason why big drug companies like Merck have been dragging their feet in regard to pharmacogenomics may be the loss of control involved. Pharnacogenomics introduces third parties (diagnostic manufacturers and laboratories) into the tightly controlled marketing processes of drug companies. However, the acquisition of diagnostic companies would eliminate this concern.

Genes May Explain Some COX-2 Drug Risks

In related news, a study published in the January issue of the journal *Gastroenterology* showed that genetics may explain as much as 30% of the differences in how people respond to painkillers like COX-2 inhibitors. The findings could eventually help physicians predict who should not take COX-2 inhibitors, which can greatly raise the risk of a heart attack in some patients.

"Exploitation of variability in response can lead to tests which identify patients most likely to benefit or suffer from drugs," said study author Susanne Fries, M.D., from the University of Pennsylvania School of Medicine. "Our study provides a starting point for the development of diagnostics that will let us conserve benefit while managing the risk of COX-2 inhibitors," she added.

Merck pulled its COX-2 inhibitor (Vioxx) from the market in September 2004 after a study showed it doubled the risk of heart attack and stroke in people who took the drug for at least 18 months. And in April 2005, Pfizer suspended sales of its COX-2 inhibitor Bextra and now includes a strong "black box" warning for its COX-2 Celebrex.

"The use of any drug involves a mix of benefits and risks. The problems with COX-2 inhibitors were real, but involved less than 2% of patients who were taking them," added Garret FitzGerald, M.D., director of Penn's Institute for Translational Medicine.

Affymetrix To Open Reference Laboratory

Affymetrix (Santa Clara, CA) has announced plans to open a CLIA-certified laboratory to accelerate the adoption of its GeneChip microarrays in clinical practice. The new lab ("Affymetrix Clinical Labs") will be located at the company's West Sacramento facility and is expected to begin performing tests in the second half of this year. Available services will include Affymetrix's commercial catalogue and custom assays such as gene expression monitoring assays, DNA analysis assays, and chromosomal copy number.

Roche Diagnostics Posts Sluggish 2005 Revenue Growth

Severin Schwan

Roche Group (Basel, Switzerland) reports that sales at its diagnostics division grew by a sluggish 4% last year to 8.243 billion Swiss francs (USD $6.388 billion); operating profit slipped by 1% to 1.687 billion Swiss francs (USD $1.307 billion). In contrast, sales at Roche's pharmaceutical division grew by 25% to 27.268 billion Swiss francs (USD $21.311 billion) in 2005. These results may explain the recent management changes at the diagnostics division *(see DTTR, February 2006, p. 4)*.

At a media conference in Basel, Switzerland, on February 1, Severin Schwan, the new head of Roche Diagnostics, called 2005 a "difficult year for Roche Diagnostics." In particular, the company's glucose monitoring business grew by only 3% worldwide—well below the market average. Schwan attributed this to declining sales in the Accu-Chek Advantage monitor and the late launch of the successor product, Accu-Chek Aviva.

Schwan also said that sales in the division's clinical chemistry segment declined by 1% worldwide due to downward pricing pressure. On the bright side, Roche's immunochemistry line grew by 15% worldwide led by record placements of Elecsys and E170 systems and strong demand for the Elecsys proBNP test.

On a geographic basis, Roche saw its weakest diagnostics growth in the United States, down 2%, while growth in Asia/Pacific was strongest, up 13%.

On the topic of personalized medicine, a reporter asked why Roche's AmpliChip CYP450 microarray did not seem to be meeting sales expectations. Schwan answered: "I am convinced, as was Heino von Prondzynski, that we at the Roche Group have the best cards in our hands with regard to a connection between pharmaceuticals and diagnostics and the further development of applications. I believe AmpliChip is the perfect example. In 2005, thirty installations were made on a worldwide basis. With regard to evaluating this product, some labs in the United States are already offering this online. So this project is up and running, and I am as much taken by storm as you are."

In terms of future personalized-medicine tests, Schwan highlighted Roche's Lightcycler SeptiFast Test, a real-time PCR test designed to identify the 25 most important bacterial and fungal species causing bloodstream infections. The test results are provided in about six hours (versus days for current blood culture methods) and allow physicians to prescribe specific therapies. Schwan noted that blood poisoning causes approximately 200,000 deaths each year in the United States alone. SeptiFast became available in Europe last year, but a Roche spokeswoman tells *DTTR* that a timetable for U.S. launch is not yet available.

Roche Diagnostics 2005 Financial Results

	in millions of CHF	in millions of U.S. dollars	YOY % Change in local currencies
Total diagnostics revenue	8,243	$6,388	4
Diabetes Care	2,886	2,237	3
Centralized Diagnostics	2,906	2,252	5
Molecular Diagnostics	1,171	907	5
Near-Patient Testing	718	556	5
Applied Science	562	436	5
Operating profit	1,687	1,307	-1

Source: Roche

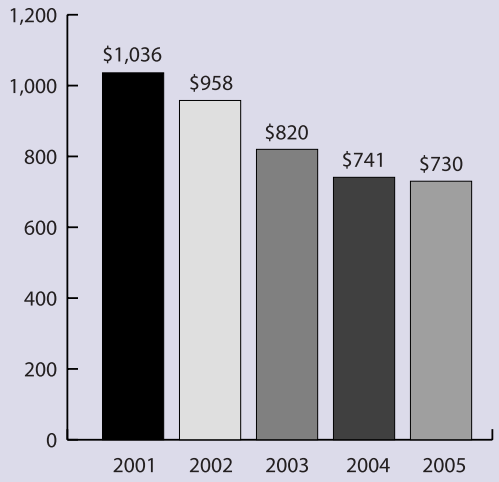
Abbott Diagnostics Stems U.S. Market Share Losses

Abbott Laboratories (Abbott Park, IL) reports that revenue at its U.S. clinical diagnostics business was nearly flat last year, dipping just 1% to $730 million. That's nothing to write home about, but it's a big improvement from the market share losses Abbott's diagnostics business sustained between 2001 and 2004, observes *DTTR*.

On a January 24 conference call, Abbott executives said the strongest areas of revenue growth within the diagnostic division were molecular (up 30%) and point-of-care testing (up 24%).

In addition, Abbott reported that U.S. revenue from its self-monitoring blood glucose business grew by 38% to $522 million in 2005 from $378 million in 2004, partly due to its acquisition of TheraSense in April 2004.

Abbott's USA Clinical Diagnostics Revenue* *($ millions)*



*excludes self-monitoring blood glucose business
Source: Abbott financial reports

Separately, UBS Investment Research analyst Benner Ulrich says that one reason why Abbott's overall diagnostics business may not be growing faster is because the company does not appear to be offering significant discounts. According to a fourth-quarter 2005 UBS survey completed by 298 hospitals and independent labs, 71% of respondents indicated that Abbott has not been giving discounts. Among participants reporting discounts, 8% (24/298) reported 0-5% discounts; 10% (29/298) indicated 5-10% discounts; and only 3% (9/298) reported discounts of over 20%.

When asked about key issues impacting the industry: 1) automation/lab staffing shortages; 2) molecular diagnostics; and 3) increasing demand for point-of-care testing were cited most frequently.

Survey participants indicated that automation should be advertised and explained more thoroughly so that labs would have more accurate expectations on how automation can be used to compensate for the coming shortages of medical technologists.

Survey respondents also expressed their expectations of continued growth in molecular diagnostics, particularly as more FDA-cleared molecular diagnostics become available.

Percentage of Laboratories Offered Discounts by Abbott in Last Three Months

	2Q05	3Q05	4Q05
No discounts offered	68%	71%	71%
Offered discounts between 0-5%	6	4	8
Offered discounts between 5-10%	10	8	10
Offered discounts between 10-20%	10	12	8
Offered discounts over 20%	7	5	3

Source: UBS Quarterly Laboratory Vendor Surveys; n=298

Building A Molecular Diagnostics Laboratory

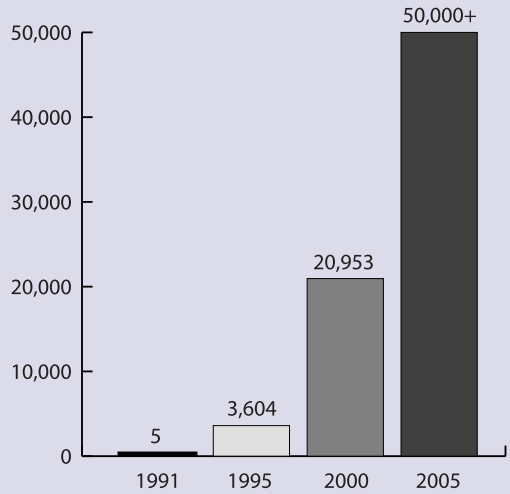
Here are some quick summaries of some of the presentations at the G-2/PSA *Building a Molecular Diagnostics Laboratory* conference:

Daniel Farkas, Ph.D.

As an example of the growth potential in molecular diagnostics, **Daniel Farkas, Ph.D.**, vice president, clinical diagnostics, **ChondroGene Inc.** (Toronto, Canada), cited the molecular pathology lab at William Beaumont Hospital (Royal Oak, MI), which performed just five tests in its first month of operation in December 1991, but performed more than 50,000 tests last year.

Although Roche's CYP450 microarray is off to a slow start in the United States, Farkas sees big potential for the test, which is initially being used to determine individualized treatments for patients on antidepressant and schizophrenia drugs. He cited statistics from the National Institute of Mental Health, which show that 5.3% of adults in the United States, or 17 million people, suffer from depression. And he noted that annual sales of antidepressant drugs in the United States exceed $3 billion. "The psychiatry department at Methodist Hospital is highly interested in CYP450," he said.

William Beaumont Hospital Molecular Pathology Laboratory Test Volumes



Source: D. Farkas presentation at G-2's *Building a Molecular Diagnostics Laboratory*

Farkas established the molecular pathology lab at William Beaumont and was its co-director until 1998. He then established a new hospital-based molecular lab at Methodist Hospital in Houston and is now an executive at ChondroGene (Toronto, Canada), which has developed a molecular testing technology for early diagnosis of cancer from blood samples. The company's first commercial product is expected to be a colon cancer test.

For laboratories performing complex inherited disease testing, access to a genetic counseling resource is a huge advantage, according to **Thomas Williams, M.D.**, vice chair of pathology at the **University of New Mexico** and director of the genetics and cytometry division of **TriCore Reference Laboratories** (Albuquerque).

Williams says that TriCore employs one genetic counselor, Joanne Milisa, who is focused on communicating cystic fibrosis and hemochromatosis test results to patients, nurses, and physicians. TriCore performs about 1,100 cystic fibrosis and 160 hemochromatosis tests per year. "For the physician, the real service is being able to talk to a person and getting consultative services from MTs and lab directors," he said.

Michael Lewinski, Ph.D.

TriCore currently performs 6.2 million tests and collects $75 million of revenue per year. "Our molecular lab represents about 5% of our budget at TriCore. . . . There's no question it's making a contribution," said Williams.

Michael Lewinski, Ph.D., director of infectious diseases at **Quest Diagnostics Nichols Institute** (San Juan Capistrano, CA), believes the biggest challenge that hospital labs have with operating a molecular diagnostics laboratory is the rapidly changing technology and platforms that require continual capital investment. The biggest advantage is turnaround time.

Emory Medical Laboratoies (EML) has invested about $1 million in instruments systems for its molecular diagnostics, according to **Angela Caliendo, M.D., Ph.D.**, associate professor of medicine at Emory University School of Medicine and director of EML. For hospitals that are considering opening up a molecular lab, she cautioned, "It's a lot of money to invest in instruments if you're only going to do a small volume of tests."

Since 1999, EML's molecular lab has increased its testing volume from 9,000 tests per year to approximately 40,000 tests in 2005. Caliendo said 90% of testing volume is infectious disease related.

Examples of Medicare Reimbursement

	Chlamydia Trachomatis	*HIV-1 Viral Load*
Alabama	$31.49	$68.50
Connecticut	49.04	118.89
Florida	41.65	98.47
Georgia	27.41	72.51
Illinois	49.04	118.89
North Carolina	34.26	74.28
Virginia	45.95	97.37
National limit	49.04	118.89
Direct lab costs*	15.00	80.00

*includes reagent, technical labor, and supply costs
Source: A. Caliendo presentation at G-2's *Building a Molecular Diagnostics Laboratory* and Medicare Part B fee schedule

Caliendo called reimbursement for molecular tests a "nightmare." She cited Medicare reimbursement for HCV viral loading testing, which is set at $59.85 in Georgia (the same as Medicare's national limit). She said that EML's direct costs (reagents, tech time, supplies) are $75 per test. "We've been lobbying CMS for three years, but they haven't moved it," she added.

Caliendo also pointed out the wide disparity in Medicare reimbursement for molecular testing from state to state (see table). "The differences are astonishing and will affect whether or not you can make money," she said.

On the issue of patents in molecular diagnostics, Caliendo said, "I think they set back advances in hepatitis testing by one decade. . . . Patents have not done much at all to advance diagnostics."

The molecular diagnostics lab at the **University of Pittsburgh Medical Center (UPMC)** has seen its test volume grow from about 5,000 tests in 1998 to 20,000 tests in 2005, according to **Jeffrey Kant, M.D., Ph.D.**, director, division of molecular diagnostics, department of pathology at UPMC. In terms of the outlook for molecular diagnostics, Kant said, "I think it's going to grow dramatically. There aren't a lot of effective treatments for cancer out there."


Tricia Hughey, CEO of Unipath

Tricia Hughey, chief executive of **UniPath** (Denver, CO), highlighted the opportunities to perform a whole set of molecular tests from liquid Pap test specimens, including HPV testing, CT/NG testing, and more recently herpes simplex virus testing. UniPath currently performs 120,000 Pap tests per year and is 100% converted to liquid methods from both Cytyc and TriPath. Hughey says UniPath is now evaluating the viability of strep group B and cystic fibrosis genetic testing on liquid Pap tests.

UniPath operates an independent freestanding lab and employs 26 pathologists plus a support staff of 130 people that serve the eight hospitals in the Denver metropolitan area. At six of the eight hospitals, UniPath owns and operates the histology departments.

On the subject of United Healthcare's plans to contract all of its outpatient lab and pathology work to regional lab networks throughout the country, Hughey said, "I think it's a huge threat to us. It will cut into the viability of the physician-pathologist relationship. State associations need to stand up and beat their chests about this."

"Our outreach lab has been a tremendous advantage to our molecular diagnostics lab," said **Jane Rachel**, MT, manager of molecular diagnostics and flow cytometry at **Saint Luke's Hospital and Regional Laboratories**. She said that Saint Luke's funded the development of its molecular lab with $100,000 in 1994 and introduced its first assays in 1995; it currently performs more than 25,000 tests per year.

In addition to clinical lab work, Saint Luke's performs molecular tests for pharmaceutical companies as well. "The amazing thing about clinical trials is that they pay what you bill," she noted.

Jane Rachel from Saint Luke's Hospital

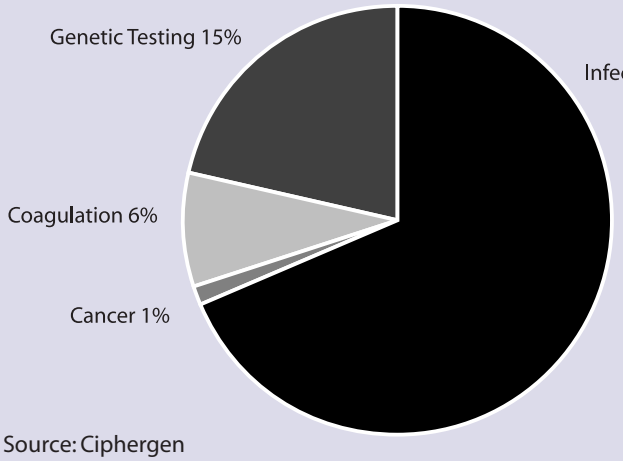
To improve turnaround time and reduce wasted reagents, Saint Luke's switched from scheduled runs (Mon., Weds., Fri. at 1:00 P.M.) for quantitative cytomegalovirus to starting runs whenever nine samples were pending. The result was: 1) turnaround times decreased by 20%; 2) annual reagent savings totaled $68,370; and 3) the relationship between the lab staff and bone marrow transplant staff improved dramatically.

New technologies are rapidly transforming biomarker discoveries into commercial diagnotics, noted **Carol Berry**, head of corporate marketing and North American sales for **Ciphergen** (Fremont, CA). She cited the six years it took to develop an HIV monitoring test as compared with the eight months the industry took to develop a test for West Nile Virus.

Ciphergen is developing proteomic-based tests for cancer, including ovarian, breast, and prostate cancer. In July 2005, the company entered into a three-year agreement with Quest Diagnostics to collaborate on bringing three proteomic tests to market. Quest has exclusive rights to commercialize these tests in the United States. In addition, Quest purchased 6.2 million shares of Ciphergen stock, or approximately 17.4%, for $15 million and loaned the company another $10 million. Quest's decision on which types of tests it plans to commercialize is likely to be announced sometime this year, according to Berry.

Berry said the U.S. molecular diagnostics market is currently seeing its greatest growth in DNA-based HPV testing, HIV and HCV, cystic fibrosis, and blood bank screening for hepatitis B and West Nile Virus.

The U.S. Molecular Diagnostics Market



Source: Ciphergen

Pathology Associates Medical Laboratories (PAML) established its molecular diagnostics laboratory in 1999, according to **Bassem Bejjani, M.D.**, who is lab co-director. Bejjani says cystic fibrosis genetic analysis has been one of the fastest-growing tests at the molecular lab, which is located at Sacred Heart Medical Center (Spokane, WA)—the owner of PAML.

The molecular lab is currently performing about 650 cystic fibrosis tests per month, or almost double the amount two years ago. Bejjani thinks volumes will continue to grow given that only about 25% to 30% of OB/GYN offices routinely recommend the test.

Bejjani believes molecular cancer testing is ready to explode: "You use it for diagnosis, prognosis, and therapy decisions versus genetic tests that are used only once."

Bejjani is less optimistic on the outlook for CYP450 genotyping for antidepressant and schizophrenia drug prescriptions. "Psychiatrists are not early adopters and are not likely to order this test soon. Adoption will happen, but I don't know when. It will depend on physician education," he observed.

Bejjani's advice to labs that are marketing a new test: 1) keep the message simple; 2) target specific clients; 3) identify educational opportunities (e.g., grand rounds, local/regional provider meetings, etc.); 4) focus on the message; and 5) follow up.

The FDA has been a little ambivalent in terms of defining their role in regulating (or not regulating) analyte specific reagents (ASRs), particularly for molecular diagnostics, noted **Peter Kazon**, senior counsel at the law firm **Alston & Bird** (Washington, DC). "They [the FDA] are asking, 'Is it really appropriate that a manufacturer puts a product out there and doesn't tell you how to use it?'"

Kazon noted that the FDA has the power to regulate ASRs under section 510(1) of the Food & Drug Modernization Act of 1997, which states:

> *Even where it would otherwise be Class I, device is not exempt if "intended for a use which is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury."*

As a result, even Class I and II ASRS can be subject to FDA regulation (e.g., Roche's Amplichip CYP450 microarray), according to Kazon. "They [the FDA] are sort of like a ninja hiding in the darkness, and you never know when they are going to leap out and attack," he observed.

The Centers for Disease Control and Prevention (CDC) published a Notice of Intent to establish a new genetic testing specialty under CLIA in May 2000. And, after five years, Kazon said the CDC was now working on a proposed rule that will invoke heightened standards for genetic testing labs. "It's something we can expect to see in the future," he said.

In terms of reimbursement for new genetic tests, Kazon said, "The challenge for the industry in the next few years will be getting CMS out of the box of linking new tests to old test codes [cross walking]."

JAMA Study Touts BladderChek Test For Recurrent Cancer

The American Cancer Society estimates that over 63,000 new cases of bladder cancer were diagnosed in the United States in 2005 (over 47,000 men and 16,000 women), and over 13,000 people died of the disease (nearly 9,000 men and 4,000 women).

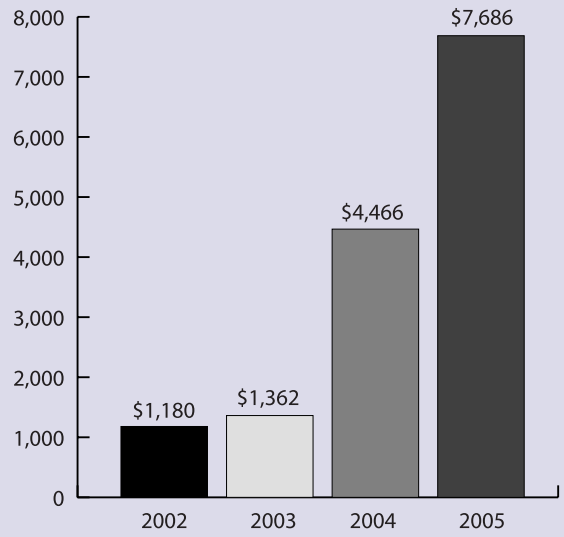
The NMP22 BladderChek Test, a CLIA-waived urine test, can significantly increase the detection of recurrent bladder cancer, finding 99% of the malignancies when used with cystoscopy, according to a study published in the January 18 issue of the *Journal of American Medical Association (JAMA)*.

The NMP22 test is CLIA waived and measures the level of NMP22, which is a type of protein in the urine. If the NMP22 is elevated, it is a sign of bladder cancer.

The study, conducted from September 2001 to February 2002, included 23 academic, private practice, and hospital facilities in nine U.S. states and enrolled 668 patients with a history of bladder cancer. Prior to undergoing cystoscopy, patients provided a urine sample for analysis of NMP22 protein and for cytology testing.

Bladder cancer was diagnosed in 103 patients. Cystoscopy alone identified 91.3% of the cancers. The combination of cystoscopy with the NMP22 assay detected 99.0% of the malignancies. The NMP22 assay detected eight of nine cancers that were not visualized during initial cystoscopy, including seven that were high-grade. The sensitivity and specificity of the NMP22 test alone were 49.5% and 87.3%, respectively. Cytology based on voided urine detected only three of the malignancies missed during initial cystoscopy and did not significantly increase the sensitivity of cystoscopy (94.2%).

NMP22 BladderChek Test Sales *($000)*



Source: Matritech

The study was funded by the developer of the test, Matritech (Newton, MA), which sells the test for $15 to $20 each. Medicare reimburses the test under CPT code 86294 at $25 to $30, depending on the carrier.

In 2005, Matritech increased the sales of its NMP22 BladderChek Test by 72% to $7.7 million. On a February 7 conference call, Stephen Chubb, chief executive of Matritech, suggested that sales of NMP22 are likely to grow to roughly $11 million to $12 million this year. Matritech currently sells the test through a direct salesforce in the United States and Germany, and is developing distribution channels in Spain, Italy, and Japan.

Correction: The February Issue of *DTTR* inaccurately described GlaxoSmithKline's decision to use Gen-Probe's PCA3 test in its clinical trials for the cancer therapy drug Avodart. In fact, the clinical trials will involve 8,000 patients in 27 countries. GSK will use the PCA3 test, as well as the traditional PSA test, to see if Avodart can reduce the risk of prostate cancer in men at increased risk of the disease.

IVD Stocks Up 6%; OraSure And Immucor Jump

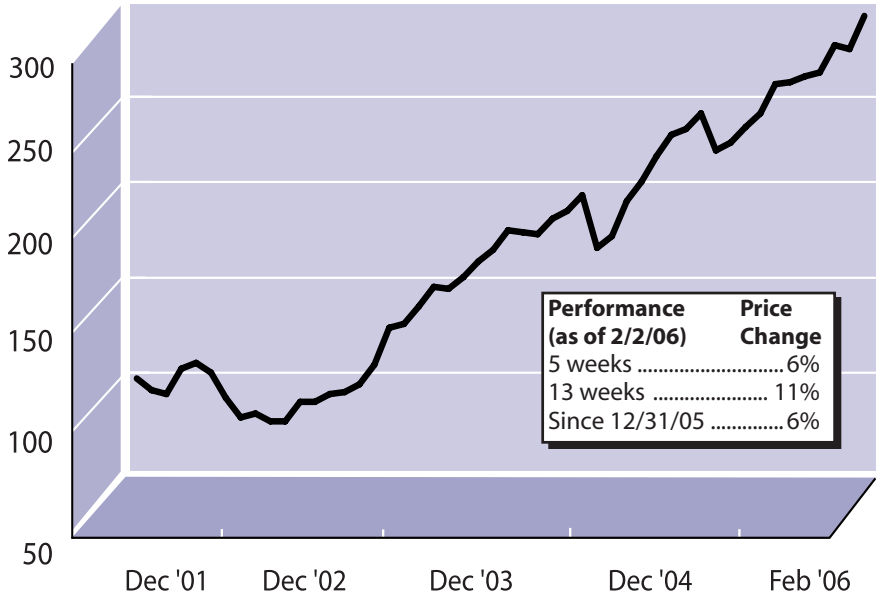
The 22 stocks in the G-2 Diagnostic Stock Index rose by 6% in the five weeks ended February 2, with 14 stocks up in price and eight down. Year to date, the G-2 Index is up 6%, compared with 2% for the S&P 500 Index and 3% for the Nasdaq.

OraSure Technologies (Bethlehem, PA), which makes the OraQuick Rapid HIV-1/2 Test, jumped 30% to $11.50 per share for a market cap of $511 million. The company got a boost from President Bush's State of the Union Address on January 31, which included the announcement of an initiative to increase efforts to prevent, treat, and ultimately defeat HIV/AIDS. The initiative includes a proposal to distribute rapid HIV test kits in areas of the country with the highest rates of newly discovered HIV cases and the highest suspected rates of undetected cases.

Immucor (Norcross, GA) rose by 29% to $30.08 per share for a market cap of $1.3 billion. Immucor was lifted by the news that Blood Systems Laboratories (BSL-Tempe, AZ) had ordered eight of its Galileo instrument systems for antibody screening and blood typing. BLS specializes in high-volume blood-donor testing. Its two national labs test more than 2.6 million blood donations each year for more than 75 blood and tissue collection sites.

Meanwhile, **Affymetrix** (Santa Clara, CA), which makes DNA chips, slipped 20% to $38.04 per share for a market cap of $2.5 billion. The company reported lower-than-expected fourth-quarter net income of $24.8 million, or $0.35 per share, compared with $27.1 million, or $0.41 per share, a year earlier; revenue rose to $111.5 million from $107.7 million.

G-2 Diagnostic Stock Index



Source: The G-2 Diagnostic Stock Index is tabulated weekly by *DTTR* from the average percentage change in the stock price of 22 IVD companies.

Avg. % Price Change, Five weeks ended 2/2/06

UP	Price	% Chg
Abaxis	$19.76	20%
Abbott Labs	42.42	8
Beckman Coulter	59.17	4
Becton Dickinson	63.64	6
Bio Rad	66.31	1
Cholestech	10.81	9
Cytyc	28.70	9
Diagnostic Products	50.39	4
Digene	32.72	12
Immucor	30.08	29
Inverness Medical	26.25	11
Meridian	24.03	19
OraSure	11.50	30
Third Wave	3.25	9
DOWN		
Affymetrix	38.04	-20
Bayer	41.22	-1
Biosite	49.34	-12
Dade Behring	39.99	-2
Gen-Probe	48.22	-1
Johnson & Johnson	57.65	-4
Quidel	9.99	-7
Ventana	39.98	-6

G-2 Insider

A quick look at pathology group send-out trends: There are some 12,000 board-certified pathologists actively practicing in the United States today, and approximately 70% work in solo practices or group practices. Their send-outs cases to reference labs represent more than $1 billion per year in revenue, according to Washington G-2 estimates.

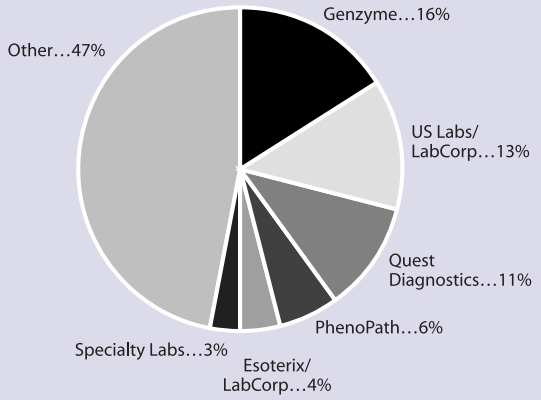
So what exactly are these pathology groups sending out? Well, 27% of pathology groups say hematopathology cases are their most frequently referred procedures, according to a survey of 75 pathology groups conducted by the pathology business services firm PSA (Florence, SC). The next most frequently referred procedures are HER2/neu studies (23%) and antibodies not commonly used (20%).

Which category of procedures do you most often request?

Hematopathology cases	27%
HER2/neu studies	23%
Antibodies not commonly used	20%
Complex cases, in general	8%
Just occasional, very difficult cases	8%

Source: PSA July 2005 survey

When utilizing a reference laboratory, where do you most often send your tests?



Source: PSA July 2005 survey

LabCorp (including US Labs and Esoterix) is getting the biggest share of the work, 17%. Genzyme Genetics is next with 16%, followed by Quest Diagnostics, 11%; PhenoPath Laboratories, 6%; and Specialty Laboratories, 3%.

The top five factors that surveyed pathology groups said they use when choosing a reference pathology lab were: 1) quality results; 2) turnaround time; 3) experts on staff; 4) performance on technical component; and 5) pathologist accessibility.

Company References

Affymetrix 408-731-5000

ChondroGene 416-650-0060

Ciphergen 510505-2100

Matritech 617-928-0820

Merck 908-423-1000

PSA 843-664-4300

Roche Diagnostics 317-521-2000

UniPath 303-512-0888

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