Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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CONTENTS

WASHINGTON G-2 REPORTS

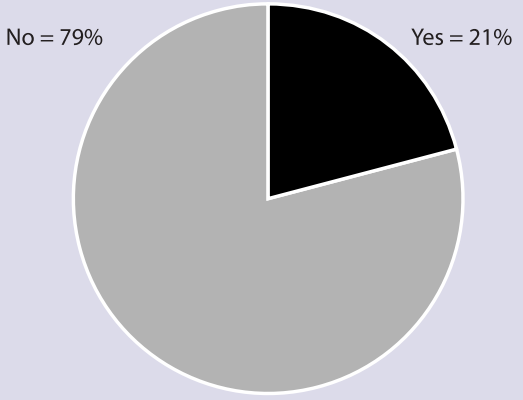
Established 1979

Pap Testing Growing, Gaps In Knowledge Of Screening Guidelines Persist

Since 2003, the cytology market in the United States has grown 60% and is now valued at $2 billion. While Pap test volumes have increased steadily, a recent survey by the National Cancer Institute (NCI) shows that most American women are unaware in the change in guidelines recommending a Pap test every three years for healthy adult women.

Although 93% of female respondents to NCI's Health Information National Trends Survey (HINTS) report ever having had a Pap test to screen for cervical cancer, more than three-fourths (79%) of those surveyed were not aware of the guidelines that recommend a Pap test every three years. And, although human papilloma virus (HPV) is a major cause of cervical cancer, most American women surveyed (61%) had never heard of it. For an in-depth look at the markets for anatomic pathology and cytology, see *Inside the Diagnostics Industry*, pp. 5-8.

Most medical organizations now recommend a Pap test every three years for healthy adult women. Have you heard about this change in guidelines?



Source: 2006 NCI Health Information National Trends Survey

Genzyme Introduces Pharmacogenomic Test For Lung Cancer

Genzyme (Cambridge, MA) has launched a test to help identify non-small cell lung cancer (NSCLC) patients who may not respond to targeted therapies. The company's KRAS Mutation Analysis can help identify NSCLC patients who test positive for specific mutations in the KRAS gene that have been associated with resistance to certain chemotherapeutic drugs known as tyrosine kinase inhibitors (TKIs), including erlotinib (Tarceva) and gefitinib (Iressa).

Between 15% and 30% of NSCLC tumors have mutations in the KRAS gene, and this information can be vital to making treatment decisions. KRAS mutations are found more frequently in patients who show limited

➥ *p. 2*

An estimated 162,460 people in the United States will die of lung cancer this year, which is more than the number of those who die each year from colon, breast, and prostate cancers combined.

▲ **Pharmacogenomic Test For Lung Cancer,** *from page 1*

clinical response or who have a shorter time to disease progression with TKI treatment. Genzyme is the only national commercial laboratory offering KRAS Mutation Analysis. In addition to this new assay, the company offers two other tests that help identify NSCLC patients likely to respond to TKI therapies: EGFR by fluorescence in-situ hybridization (FISH), which was launched earlier this year and detects amplification of the EGFR gene, and EGFR Mutation Analysis Assay, which detects the presence of EGFR mutations in patients with NSCLC.

Genzyme holds exclusive, worldwide diagnostic rights to the discovery of EGFR gene mutations in NSCLC tumors. Researchers are now investigating the presence of the same EGFR mutations in other tumor types.

Magellan Biosciences Buys Trek Diagnostic Systems, Gets $50M In Financing

Magellan Biosciences (Chelmsford, MA) has acquired Trek Diagnostic Systems (Cleveland, OH), a microbiology company that specializes in clinical diagnostic products for infectious diseases. Financial terms of the deal were not disclosed.

The acquisition is part of two-year-old Magellan's strategy to expand its presence in clinical diagnostics and provides the company with entry into hospital-based laboratories. Trek will operate as a wholly owned subsidiary of Magellan under the Trek Diagnostic Systems brand. Magellan plans to retain Trek's management team and its approximately 150 employees, which currently work from offices in Sun Prairie, Wisconsin, and West Sussex, England, as well as Cleveland.

The purchase of Trek expands Magellan's portfolio to four companies that supply the clinical diagnostic markets. In addition to Trek, the company owns ESA Biosciences, Dynex Technologies, and TekCel.

And reportedly, more acquisitions are on the way thanks to Magellan's newly completed round of debt and equity financing, which brought to its coffers $50 million: $34 million in equity and $16 million in debt financing. Equity investors included Abingworth Management, Hambrecht & Quist Capital Management, KBL Healthcare Ventures, and Ampersand Ventures.

According to Robert J. Rosenthal, Magellan's CEO and president, the company will now focus on expanding its presence in products for clinical diagnostics, hospital-based labs, and point-of-care testing by diversifying its diagnostic platforms.

Zila Focuses On Oral Cancer Market With Acquisition of Pro-Dentec

As it looks to shift its focus to oral cancer screening, Zila Pharmaceuticals (Phoenix, AZ) has completed its $34 million acquisition of Professional Dental Technologies (Pro-Dentec; Batesville, AK), a privately held designer, manufacturer, and marketer of dental products. Zila recently sold its Nutraceuticals business for $37.5 million as part of its plan to concentrate on the cancer screening market.

With annual revenues of approximately $35 million, Pro-Dentec will give Zila a powerful network for distributing its oral cancer products to dental offices nationwide. Zila completed a $40 million private placement of equity and debt through Roth Capital Partners to facilitate the acquisition.

Every year, Pro-Dentec conducts about 115 continuing education seminars, which are prime venues for educating dental professionals on the importance of oral cancer screening. Zila plans to leverage Pro-Dentec's sales and marketing to grow ViziLite Plus, a point-of-care oral cancer screening product, with an initial focus on the dental market. The company aims to establish ViziLite Plus as the new standard of care for the early detection of oral abnormalities that could lead to cancer.

Meanwhile, Zila is awaiting FDA approval of OraTest, its oral cancer test that has been available outside of the United States since 2000. Administered at the point of care, OraTest is designed to detect asymptomatic, early-stage cancerous lesions. The test consists of a sequence of three rinse solutions and takes five to 10 minutes to administer. The test must be repeated 10 to 14 days later to confirm suspicious lesions.

Illumina To Acquire Solexa For $600M: The Next Genomics Powerhouse?

Genetic analysis company Illumina (San Diego, CA) has announced that it will acquire Solexa (Hayward, CA), a leader in genome sequencing, in a stock-for-stock merger valued at approximately $600 million. Illumina, best known for its BeadArray genotyping products, has also agreed to invest $50 million in Solexa in exchange for newly issued shares in the company. The transaction is expected to close by the end of the first quarter.

With its 1G Genome Analyzer platform, Solexa will give Illumina a powerful presence in the $1 billion sequencing market and expand its genetic analysis portfolio to include genotyping, gene expression, and sequencing. The combined company will focus on developing products that integrate genotyping and sequencing, minimize costs, and maximize throughput.

"Together we expect to reach and exceed the milestone of the $100,000 genome," said Solexa CEO John West, referring to the goal of a platform that would enable human genome resequencing at a cost of less than $100,000 per sample. West will join Illumina as senior vice president and general manager of the sequencing business. Illumina plans to maintain Solexa's operations in both California and Cambridge, England, and two members of Solexa's board of directors will join Illumina's board of directors.

Bio-Rad Closes On $20m Purchase of Ciphergen's Proteomics Biz

Bio-Rad Laboratories (Hercules, CA) is betting on proteomics. The manufacturer and distributor of clinical diagnostics and life sciences research products has purchased the proteomics instrument business of molecular diagnostics company Ciphergen Biosystems (Fremont, CA) for approximately $20 million in cash.

Bio-Rad struck a separate supply agreement to supply instruments and reagents to Ciphergen's diagnostics business and to make a $3 million equity investment in the company.

Ciphergen's proteomics instrument business includes the company's Surface Enhanced Laser Desorption/Ionization (SELDI) technology, ProteinChip arrays, and accompanying software. The agreement calls for Bio-Rad to manufacture, sell, and market the SELDI technology to the life sciences marketplace for proteomics applications, such as biomarker discovery and validation. Ciphergen will retain exclusive rights to the diagnostics market.

Gail Page, president and CEO of Ciphergen, describes the agreement with Bio-Rad as a way to "accelerate [Ciphergen's] transformation into a leading specialized diagnostics provider." After the Bio-Rad transaction, Ciphergen will have about 40 employees dedicated to commercializing diagnostic tests, primarily in oncology with an initial focus on ovarian and prostate cancer. Last year, the company entered a three-year strategic alliance with Quest Diagnostics to develop and commercialize proteomic diagnostic tests from its pipeline, including the first proteomics-based test for ovarian cancer.

Response Biomedical, 3M To Develop POC Infectious Disease Tests

Response Biomedical Corporation (Burnaby, British Columbia) has closed on an $8 million equity investment by 3M Company (St. Paul, MN), which gives 3M about 13% ownership in the point-of-care diagnostic test company. 3M will have exclusive rights, through its medical division, to pursue the development and commercialization of immunoassays for infectious diseases, using Response Biomedical's RAMP testing platform.

The agreement calls for Response Biomedical to be responsible for the development and manufacturing of the RAMP-based products (primarily readers and individual test cartridges), with 3M handling clinical and regulatory issues. The first rapid tests developed, manufactured, and marketed under this agreement will be for *Staphylococcus aureus* and Flu A/B. Marketing for these initial products is slated to begin later this year.

According to Bill Radvak, CEO of Response Biomedical, the agreement with 3M is part of the company's broader strategy to commercialize their RAMP platform by partnering with bigger players that have well-developed sales and marketing teams. The RAMP platform consists of a portable fluorescent reader and single-use test cartridges. It produces results in less than 15 minutes.

Response Biomedical recently launched their BNP test, which assists in diagnosing and managing congestive heart failure, in Japan in partnership with Shionogi & Co. The company also has initiated clinical trials to obtain FDA clearance for its NT-ProBNP congestive heart failure test, which it licensed from Roche Diagnostics. They already have gained FDA and Health Canada market clearance for the RAMP reader and tests for troponin 1, myoglobin, and CK-MB.

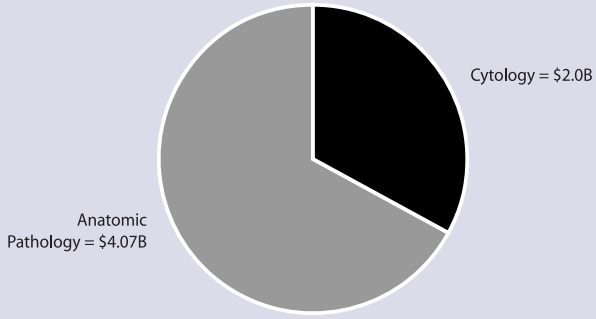
Anatomic Pathology And Cytology: Continued Growth Driven By Pap Testing

According to the American Society for Clinical Pathology, there were between 13,000 and 14,000 board-certified pathologists actively practicing in the United States last year.

Market Overview

The combined U.S. anatomic pathology and cytology market was estimated by Washington G-2 Reports to be slightly over $12 billion in 2006. The cytology market was worth approximately $2.0 billion (4% of the total laboratory market) in 2006; the anatomic pathology market in 2006 was approximately $4.07 billion, or 8.2% of the total laboratory market.

The Anatomic Pathology & Cytology Market, 2006

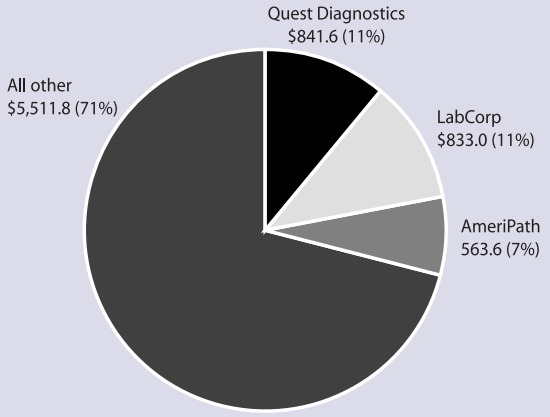


Source: Washington G-2 Reports

From 2003 to 2006, the cytology market grew a total of 60%, from $1.25 billion to $2 billion, driven by the adoption of mono-layer Pap testing methods, which are more expensive than the liquid-based Pap testing method. The anatomic pathology market dropped 29% from 2003 to 2006, from $5.75 billion to $4.07 billion. Although there is growth in test volumes, anatomic pathology revenue losses are driven by steady and significant decreases in the professional component reimbursement. Growth in the overall cytology and anatomic pathology market has been driven by the 60% increase in the cytology market from 2003 to 2006.

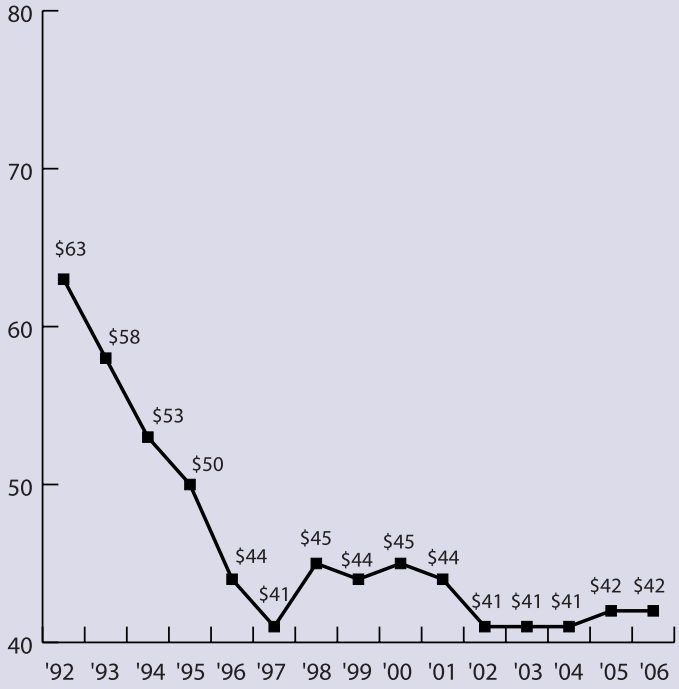
Despite consolidation efforts in the anatomic pathology market, especially the acquisition of Dianon by LabCorp, the anatomic pathology/cytology market remains fragmented. LabCorp's efforts to grow in this area, in particular, have paid off with an 11% ($833.0 million) market share in 2005, compared to their 6% ($485 million) market share in 2003, as noted in *Washington G-2 Reports Laboratory Industry Strategic Outlook 2005*. Although AmeriPath has increased revenue from $485 million in 2003 to $563.6 million in 2005, their market share has remained flat at 7%. Quest Diagnostics has actually increased their market share as

Anatomic Pathology & Cytology Market Share, 2005



Source: Washington G-2 Reports and company reports

Medicare Reimbursement for Professional Component of CPT 88305*



*Unadjusted for geographic practice cost differences.
Source: Medicare physician fee schedules, 1992 to 2006.

well, from 7% ($475 million) in 2003 to 11% ($841.6 million) in 2005. Slightly over 71% of the market is held by thousands of other pathology groups, independent labs, and hospitals across the country. Washington G-2 Reports expects this segment to be an area of strong growth for both large independent laboratories and for smaller institutions and pathology groups.

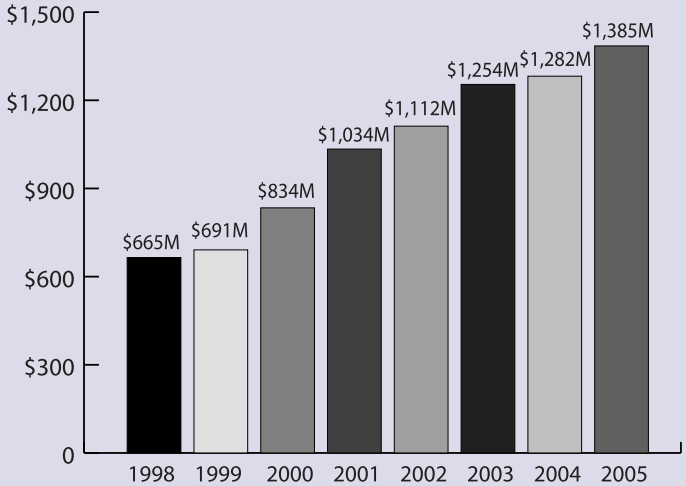
A Look At Reimbursement

It is possible to get an overview of reimbursement trends for anatomic pathology services by examining the changes in Medicare payment for CPT 88305. The most frequently billed anatomic pathology procedure, CPT 88305, is for gross and microscopic exam, Level IV.

From 1992 through 2006, Medicare reimbursement for the professional (pathologist) component of CPT 88305 has shown a steady decline, though it rose slightly from 1998 through 2001. In 1992 the professional reimbursement from Medicare was $63, having fallen to $42 in 2005 and 2006.

In 2005, Medicare cut reimbursement for flow cytometry procedures by 40% to 50%. However, pathologists and laboratories received an 8.7% increase in the reimbursement for CPT 88305, the most commonly billed anatomic pathology code. The global reimbursement level for 88305 in 2005 (and 2006) is $103.46, up from $95.21 in 2004. The majority of this increase came via the technical (laboratory) component, which increased by

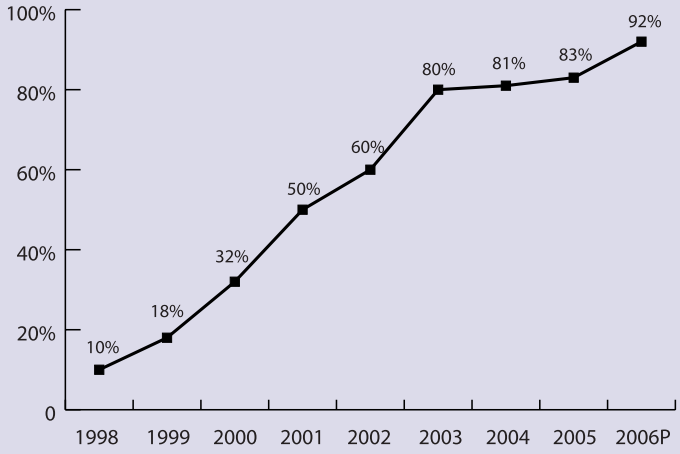
Laboratory Service Revenue from Pap Testing ($MM)



Source: Washington G-2 Reports

14.2% from $53.77 in 2004 to $61.39 in 2005. The professional (pathologist) component only increased slightly (1.5%) from $41.44 in 2004 to $42.07 in 2005. Overall this has accounted for an 8.1% increase in CPT 88305 reimbursement.

Percentage of Pap Tests Performed Using Mono-Layer Methods, 1998-2006



Source: Washington G-2 Reports

More than 80% of the Pap test market is dominated by two companies: Cytyc Corp. (Marlborough, MA) and TriPath Imaging (Burlington, NC). They both market a mono-layer Pap test (versus traditional smears). The Cytyc product, ThinPrep, was approved by the FDA in May 1996. The TriPath Imaging system, SurePath, was approved by the FDA in June 1999.

Prior to April 1, 2001, Medicare reimbursed mono-layer tests at the same rate as traditional Pap tests, which was $7.15 before Jan. 1, 2000, and a national minimum of $14.60 afterwards. After April 1, 2001, Medicare upped mono-layer Pap test reimbursement to a national cap of $28 per test, resulting in accelerated acceptance of the mono-layer tests.

Medicare only accounts for about two million Pap tests each year. Medicare reimbursements, however, are a standard for how managed care companies and third-party payers set their reimbursements.

Washington G-2 Reports estimated that in 1999, 18% of the 51 million Pap tests performed in the United States were done using mono-layer methods. The

Revenue for Cytyc Corporation and TriPath Imaging, 2005 to 2006* ($MM)

Company	*2005 Revenue*	*2006 Revenue**	*Percent Change*
Cytyc Corporation	$304.0**	$329.6	8.4%
TriPath Imaging	$10.8	$14.0	29.6%

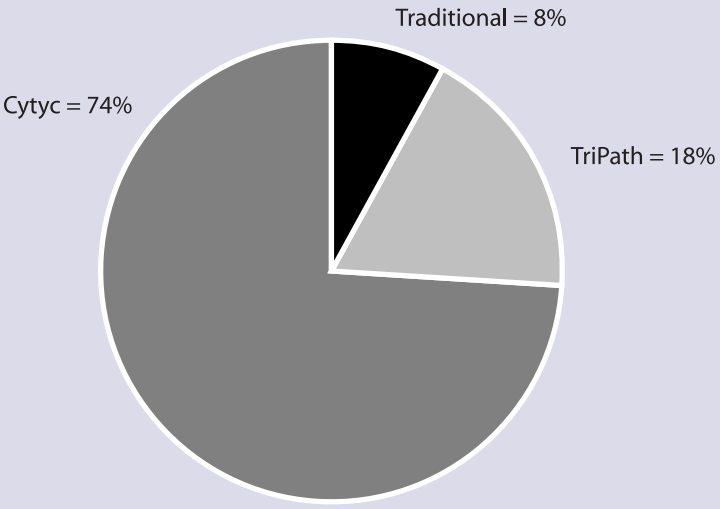
*Projections based on reported quarterly earnings.

**Based on Cytyc's domestic diagnostic products revenue.

Source: Company reports

National Cancer Institute estimates there were approximately 55 million Pap tests performed in the United States in 2005 and 2006. The market share for mono-layer was 83% in 2005, and based on projections of revenue increases from 2005 to 2006 for both Cytyc and TriPath, Washington G-2 Reports believes mono-layer Pap testing will account for 92% of the Pap testing market share. Into 2007 and beyond, mono-layer Pap testing will likely replace traditional methods completely.

Market Share for Pap Test Vendors, 2006P



Source: Washington G-2 Reports; company reports

Although it has been predicted that growth in mono-layer Pap testing would slow down, it doesn't appear to be. Although the test is more expensive than the traditional method, there has long been concern among physicians over reliability of the traditional Pap testing methodology. Several studies indicate the new techniques improve detection of precancerous lesions by 65% in screening populations and 6% in high-risk populations when compared with the conventional Pap smear. They also reduce the likelihood of a false-positive diagnosis through improving specimen quality. This, far more than cost, is probably driving the speedy growth in mono-layer Pap testing market penetration.

Approximately 74% of the 55 million Pap tests performed in the United States in 2006 use Cytyc's ThinPrep, 18% use TriPath, and 8% use the traditional Pap testing method.

Pap Testing at the Largest U.S. Laboratory Companies, 2006

	Annual Pap Volume	*Conversion to to Liquid Pap*	*Primary Vendor*
Quest Diagnostics	13,000,000	94%	Cytyc
LabCorp	9,000,000+	90%	Cytyc
AmeriPath	1,500,000	85%	Cytyc
DCL Medical Laboratories	275,000	100%	Cytyc
Sunrise Medical Labs	230,000	96.5%	Cytyc
Bio-Reference	150,000	70-80%	Cytyc
Spectrum Laboratory	145,000	98%	Cytyc
TriCore Reference Labs	125,000	96%	TriPath
Totals	24,425,000	91.8%	

Source: Washington G-2 Reports

Study Finds Delayed Breast Cancer Diagnosis Doesn't Correlate With Survival Rates, Prognosis

Clinician diagnostic delays of up to 36 months did not correlate with worsening prognostic factors for breast cancer or with survival rates for the disease, according to a study recently published in the *American Journal of Surgery*.

The study, carried out by researchers at the Oregon Health & Science University, set out to determine the impact of delay of diagnosis by clinicians on breast cancer prognostic factors (including primary tumor diameter, number of positive lymph nodes, and stage) and survival by reviewing the medical records of 40 patients whose breast cancer diagnosis was delayed by clinicians by three to 36 months.

After analyzing the data for correlations between prognostic factors and length of delay, the researchers found no significant correlations between delay and natural log of primary tumor diameter, number of positive lymph nodes, tumor grade, or pathologic stage. A higher stage correlated with decreased survival (p=.03), but delay did not.

Gen-Probe To Launch New Prostate Cancer Test In Europe

This month Gen-Probe (San Diego, CA) will launch its PCA3 assay, a molecular diagnostic test for prostate cancer, in Europe. The test detects the overexpression of PCA3 mRNA in urine. According to studies, more than 95% of prostate cancer cells show 60- to 100-fold increases in PCA3 expression levels as compared to normal cells. A list price for the test was not available at press time.

Preliminary data suggest that the PCA3 is more specific than the traditional serum prostate specific antigen (PSA) test, making this assay less likely to have false positives. PSA is produced by both cancerous and noncancerous prostate cells, and some noncancerous conditions can cause elevated PSA levels. According to Mark Emberton, M.D., a specialist in oncological urology at University College Hospital (London, England), only 25% to 30% of men who have a biopsy due to elevated PSA levels actually have prostate cancer.

Expanded Reimbursement, Clinical Use for XDx's AlloMap Test

The AlloMap molecular test, which is manufactured and performed by molecular diagnostics company XDx (South San Francisco, CA), can now be used sooner after a heart transplant—and with Medicare reimbursement virtually assured.

Commercially available since January of 2005, AlloMap detects the absence of acute cellular rejection in heart transplant recipients. The gene expression assay is a non-invasive alternative to the biopsies that have been the standard of care for monitoring heart transplant recipients. Unlike biopsies, AlloMap testing enables clinicians to monitor the immune system before tissue damage occurs.

Data from a recent study show that the AlloMap test is effective as early as two months post-transplant. The test was previously only available to patients six months post-transplant. The new clinical data also indicate that patients who are between two and six months post-transplant and have an AlloMap test score below 20 are predicted to be free from acute cellular rejection for about 12 weeks. The expanded indication will allow physicians to use the test as a monitoring tool and to personalize treatment.

Medicare recently decided to reimburse for the AlloMap test, effective on claims submitted in 2006. Because XDx's reference lab is located in South San Francisco, Medicare billing for the test goes through National Heritage Insurance Company (NHIC), the California Medicare contractor.

AlloMap's expanded indication and rosy reimbursement scenario will help molecular testing to become the standard of care in heart transplants. Many physicians predict that in the next few years, the testing will eliminate biopsies—which are invasive, painful, and expensive—altogether. According to XDx President and CEO Pierre Cassigneul, the company is seeing increased use of AlloMap testing at the top transplant centers in the United States. Meanwhile, the company is conducting clinical trials to determine the value of AlloMap testing in lung transplantation.

Qiagen Launches RUO Kit For Faster PCR

Qiagen (Venlo, Netherlands), which specializes in preanalytical sample preparation and molecular diagnostics, has launched a new line of polymerase chain reaction (PCR) products that promises cycling times of less than 20 minutes, about 75% faster than other commercially available kits.

The company's Fast Cycling PCR kit, which is being sold as a research use only (RUO) product because it has not been cleared by the FDA or under the European IVD Directive, is for general PCR applications and for amplification of complex DNA templates. Compatible with all makes and types of thermal cyclers and with current PCR assays, the kit does not require redesigning of PCR primers or protocols.

Cylex Raises $18M, Looks To Expand Beyond Transplant Testing

Cylex (Columbia, MD), which manufactures tests to measure immune activity, raised $18.4 million in its third round of venture capital funding in a deal co-led by Channel Medical Partners (Skokie, IL) and Canaan Partners (Westport, CT). Eight-year-old Cylex focuses on diagnostics for use in transplant patients and plans to use the capital infusion to expand its marketing to transplant centers and to enter new markets, including testing for HIV, hepatitis, cancer, and autoimmune diseases.

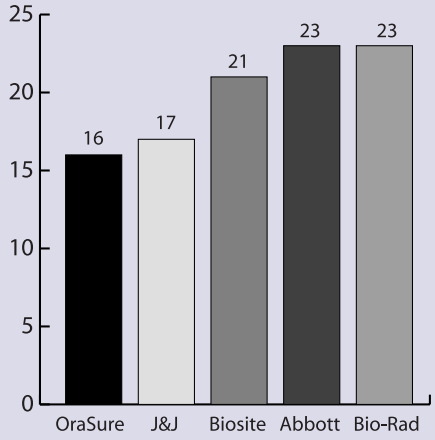
Cylex received FDA approval for Immunoknow, its cellular immune function assay, in early 2002. The blood test measures an early response to cell stimulation by detecting intracellular ATP synthesis in CD4 cells selected from blood by monoclonal antibody coated magnetic particles. The amount of ATP present in the selected cells is a measure of lymphocyte activity. Used primarily in organ transplant recipients, Immunoknow enables physicians to monitor patient response to therapies.

IVD Stocks Up 4%; Third Wave Jumps 19%

The 21 stocks in the G-2 Diagnostic Stock Index rose by 4% in the five weeks ended Dec. 8, 2006, with 16 stocks up in price, 4 down, and 1 unchanged. Year to date, the G-2 Index is up a whopping 26%, compared with a 13% gain for the S&P 500 and an 11% gain for the Nasdaq.

Third Wave Technologies (Madison, WI) jumped 19% to $5.25 per share for a market cap of $210 million. After a strong third quarter (see *DTTR*, November 2006, p. 8), the company launched its Universal Invader Program, which allows customers to design, build, and optimize assays based on Third Wave's Invader chemistry. The program includes Web-based design software that generates the designs for the oligonucleotide required to build Invader chemistry-based reactions for specific DNA targets of interest.

IVD Company P/E Ratios

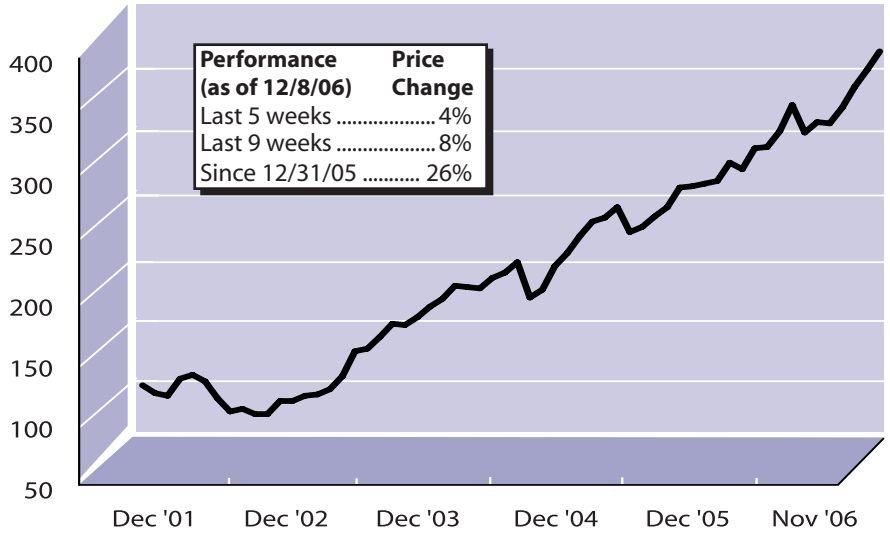


Source: *DTTR*

Quidel (San Diego, CA) was the biggest loser, falling 11% to $13.75 per share for a market cap of $459 million. Although the point-of-care diagnostics company had a strong third quarter, with total revenues up 18% to $23.7 million compared to the third quarter of last year and an aggregate increase of 22% in worldwide sales of its QuickVue Influenza tests, Strep A tests, and pregnancy tests, the stock has lost ground on predictions of a mild flu season.

Meanwhile, an analysis of the P/E ratios of IVD companies shows that **OraSure Technologies**—with a P/E ration of 16—is currently the least expensive stock. Other IVD companies with a P/E ratio of 23 or less include: **Johnson & Johnson** at 17, **Biosite** at 21, **Abbott Labs** and **Bio-Rad**, each at 23.

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 IVD companies.

Up	Price	% Chg
Abbott Labs	$47.96	1%
Bayer	52.48	4
Becton Dickinson	72.88	3
Bio-Rad	81.38	9
Biosite	49.32	8
Cholestech	18.44	15
Cytyc	27.26	2
Dade	40.11	9
Digene	48.42	3
Gen-Probe	52.06	7
Immucor	29.03	7
Inverness Medical	38.63	3
Meridian	24.04	9
OraSure	8.42	3
Third Wave	5.25	19
Ventana	41.39	5
Unchanged		
Beckman Coulter	60.77	0
Down		
Affymetrix	25.33	-2
Abaxis	19.43	-2
Johnson & Johnson	65.95	-3
Quidel	13.75	-11

G-2 Insider

New clinical practice guideline to improve accuracy of HER2 testing . . . Clinical practice guidelines are critical both in making diagnostic tests standard of care and in ensuring their accuracy. Now testing for the human epidermal growth factor receptor 2 (HER2), a predictive and prognostic marker for breast cancer, is the focus of a clinical practice guideline published this month by the College of American Pathologists (CAP) and the American Society of Clinical Oncology (ASCO).

The new HER2 guideline recommends a testing algorithm that defines positive, negative, and equivocal values for both the IHC and FISH tests. Equivocal results form a new category and require repeat testing or the use of a different test. The guideline does not recommend initial use of one test over another in most circumstances, but recommends strategies to ensure that all tests are correctly performed, validated, and reproducible.

The guideline also recommends that laboratories adhere to stringent quality improvement standards, including assessment of HER2 testing concordance of 95% with another validated HER2 test for positive and negative assay values, participation in ongoing internal testing performance evaluation, and participation in proficiency testing. Biannual examination of these activities will occur through laboratory accreditation, and CAP will require all of the laboratories it accredits to participate in HER2 proficiency testing if they want to conduct HER2 testing. For more on this new guideline, see *www.g2reports.com*.

HER2 Testing: IHC and FISH

HER2 testing helps to identify breast cancer patients that could benefit from specific treatments, while identifying others that could be spared potentially toxic and costly therapies. The two methods most commonly used to test for HER2 are immunohistochemistry (IHC) and fluorescence in-situ hybridization (FISH).

IHC testing can show how much of the HER2 protein is present on the surface of tumor cells, while FISH testing measures the number of HER2 gene copies in the nucleus of each cell.

Company References

3M 888-364-3577
Bio-Rad 800-224-6723
Cylex 410-964-0236
Cytyc 508-263-2900
Gen-Probe 800-523-5001
Genzyme 617-252-7500
Illumina 858-202-4500
Magellan Biosciences 978-856-2345
Qiagen 800-362-7737
Quidel 800-874-1517
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Zila 602-266-6700

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