Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

Vol. V, No. 7/April 2005

CONTENTS

WASHINGTON G-2 REPORTS

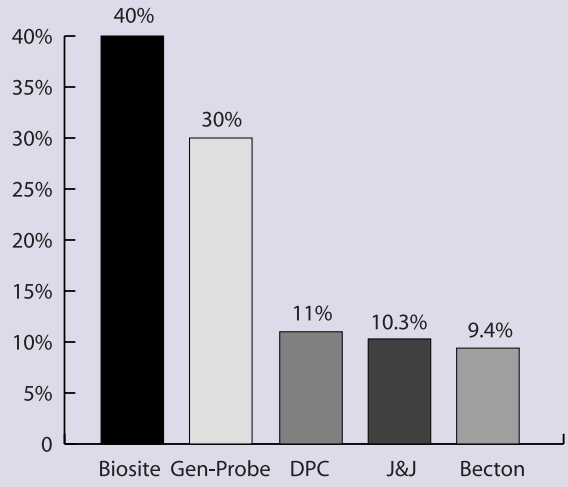
Established 1979

Worldwide IVD Sales Up 6% To $28 Billion

Worldwide IVD sales grew by 6.3% (excluding the effect of currency changes and acquisitions) to $28.3 billion in 2004, according to an exclusive analysis by *DTTR* of the financial reports from the 15 largest reagent manufacturers. Our estimate assumes that the 15 largest companies held an 85% share of the market with the remaining 15% held by hundreds of smaller companies.

The 6.3% growth rate for 2004 marks a significant acceleration from the average 5% growth recorded in 2003. Among the fastest-growing companies last year were Biosite, up 40%; Gen-Probe, up 30%; and Diagnostic Products Corp., up 11%. The only major IVD company to post negative revenue growth was Abbott Diagnostics, which slipped 1.6% to $3.4 billion after adjustments for currency changes and the acquisitions of i-Stat (January 2004) and TheraSense (April 2004). *See pages 9-10 for full details.*

Fast-Growing Large IVD Companies



Source: *DTTR* from company reports

Correlogic Responds To M.D. Anderson Study

A study that was sharply critical of fledgling blood protein-pattern tests for detecting early-stage ovarian cancer has drawn inappropriate conclusions and has nothing to do with the proteomic test that Correlogic Systems (Bethesda, MD) is now trying to bring to the clinical market, according to Peter Levine, president of Correlogic. "It's like writing a Ph.D. thesis on the Wright brother's first flight, when the rest of us are developing cargo planes," says Levine.

➥ *p. 2*

▲ **Correlogic Responds to M.D. Anderson Study,** *from page 1*

The controversial study was conducted by researchers from the University of Texas M.D. Anderson Cancer Center (Houston, TX) and published in the February 16 issue of the *Journal of the National Cancer Institute* (Signal in Noise: Evaluating Reported Reproducibility of Serum Proteomic Tests for Ovarian Cancer). The study was led by Keith Baggerly, Ph.D., a professor in the Department of Biostatistics and Applied Mathematics at M.D. Anderson, who analyzed data from another study published in the *Journal of the National Academy of Sciences* (Detection of Cancer-Specific Markers amid Massive Mass Spectral Data) in 2003.

"The hypocrisy around this [protein-pattern] testing is staggering."
—says Correlogic's Peter Levine

The *JNAS* study was authored by scientists from the State University of New York at Stony Brook, who reanalyzed two publicly available datasets, including one from an earlier study conducted by the FDA, National Cancer Institute, and Correlogic that was published in the British medical journal *Lancet* in 2002.

The *Lancet* study had reported that an experimental blood test, based on protein-pattern recognition technology, had an overall predictive value of 94% for detecting ovarian cancer versus 35% for the traditional test, CA-125 (see *DTTR*, July 2003. pp. 1, 5-7). After the *Lancet* study and other supporting work, Quest Diagnostics and LabCorp signed licensee contracts with Correlogic and made plans to begin marketing an ovarian cancer test, named OvaCheck, in late 2003 or early 2004. But these plans have been delayed by the FDA, which has questioned whether the test can be marketed as a homebrew or will need premarket clearance.

In the Stony Brook study, researchers used their own protein-pattern analysis formula to reanalyze the two datasets, and they reported finding a single pattern that could diagnose ovarian cancer across both datasets with 100% sensitivity and 100% specificity.

But the M.D. Anderson researchers compared the pattern of protein expression in the datasets analyzed by Stony Brook and found inconsistencies that were "not biologically plausible."

"We view this as a cautionary tale. If you are not careful with this new technology, whose quirks we don't fully understand, you can find results that may be due to something other than biology," said lead author Baggerly. He believes that the Stony Brook study did not demonstrate reproducibility and that the results may be explained simply by chance or by "overfitting" the data. "Reproduction of proteomic patterns across experiments remains an open question that, in our assessment, has not been answered," concluded Baggerly.

But Correlogic's Levine notes that the Stony Brook study, which Correlogic was not involved with, used two different datasets that involved two different sample handling and processing methods. As a result, the study was not an appropriate vehicle for determining reproducibility.

He adds that the *Lancet* study was essentially a proof of concept study conducted nearly four years ago. "*Lancet* was the first baby step for our technology. Nobody made a claim that we had created a test, and the *Lancet* paper was not intended as a reproducibility study. . . . We've made huge advances since *Lancet* at this point," says Levine.

He says the current OvaCheck test uses the same software to detect hidden protein patterns in the blood as in the *Lancet* study. But he says Correlogic has made major improvements in the way it prepares samples and introduces them into a mass spectrometer. He notes that OvaCheck requires frozen samples and strict uniformity of specimen processing. "I have full confidence in the reproducibility of OvaCheck," he adds.

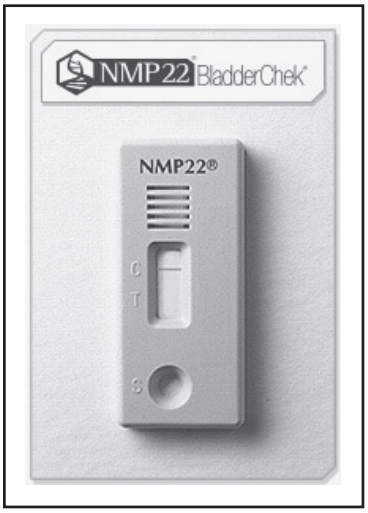
Levine notes that M.D. Anderson issued a "borderline inflammatory" press release titled "Promising Proteomics Test Is Not Biologically Plausible" that announced Baggerly's study on February 15. On the very same day, M.D. Anderson and Ciphergen Diagnostics (Fremont, CA) announced a collaboration to develop and validate new biomarkers for ovarian cancer.

Meanwhile, Levine says that Correlogic is having continuing discussions with the FDA concerning whether or not OvaCheck needs premarket clearance. Levine says Correlogic's differences with the FDA are strictly related to the agency's authority to regulate OvaCheck and that there have been no discussions concerning test accuracy or reproducibility.

"This is a classic laboratory-developed test, but if it is ultimately decided by a court that we have to make a submission to the FDA, we will. . . . But we remain convinced that the FDA is exceeding its authority by a wide margin," he concludes.

JAMA Study Cites Benefits Of Matritech's Bladder Cancer Test

Matritech Corp.'s NMP22 BladderChek test, a CLIA-waived urine test, is three times more sensitive than the conventional urine cytology microscope exam for detecting bladder cancer, according to a study published in the February 16 issue of the *Journal of the American Medical Association*. BladderChek detects levels of the nuclear matrix protein marker NMP22 in urine. NMP22 is elevated in bladder cancer cells by 20- to 80-fold and is released in the urine of bladder cancer patients.



Under the study, which was funded by Matritech, researchers tested the NMP22 tumor marker assay in 1,331 patients at high risk for bladder cancer. They determined through cystoscopy that 79 of the 1,331 patients examined had bladder cancer. The NMP22 assay was positive in 55.7% of the cases (44 out of 79 cases), while the conventional cytology test detected about 15.8% of malignancies (12 out of 76 cases).

The specificity of the NMP22 assay was 85.7% compared with 99.2% for cytology. NMP22 detected four cancers that were not visualized during initial endoscopy, including three that were muscle invasive and one carcinoma in situ.

"This demonstrated that the NMP22 test was significantly more sensitive than cytology, or the conventional laboratory test," said H. Barton Grossman, M.D., deputy chairman, Department of Urology, M.D. Anderson Cancer Center

(Houston, TX). Grossman led a team of researchers at M.D. Anderson and 23 academic, private practice, and veterans' facilities in 10 states who enrolled patients into the prospective study between September 2001 and May 2002.

Grossman cautioned that NMP22 should not be used alone to detect bladder cancer, but should be combined with cytoscopy. The study found that when cystoscopy and the NMP22 test were used together, they had a sensitivity of 94%, compared to 89% for cytoscopy alone.

Matritech Financials *($000)*

	2004	2003
Revenue	$7,483	$4,375
Operating loss	-8,368	-6,856
Net loss	-11,123	-7,878
Cash holdings	4,906	7,518
Total debt	1,782	3,194

Source: Matritech

The study also noted that the results of the NMP22 test can be read within 30 to 50 minutes in a doctor's office, while a cytology test must be performed at a laboratory.

Matritech sells its NMP22 BladderChek test for $15 to $20 each. Medicare reimburses the test under CPT code 86294 at $25 to $30 depending on the carrier. Approximately 1,000 of the 7,200 urologists in the United States that treat bladder cancer have ordered a BladderChek test, and more than half reorder it, according to Stephen Chubb, chairman and CEO.

Matritech is also developing a fully automated format of NMP22 for lab-based testing through a nonexclusive partnership with Diagnostic Products Corp. (DPC-Los Angeles, CA). DPC currently sells this product outside the United States and is conducting trials to demonstrate the substantial equivalence of this automated version to gain FDA approval.

Last year, Matritech posted a loss of $11.1 million versus $7.9 million in 2003; revenue increased by 71% to $7.5 million. As of Dec. 31, 2004, Matritech had $4.9 million of cash holding, but the company recently raised $5.9 million from a private placement of convertible preferred stock and plans to soon raise another $6.65 million.

Digene Launches Direct-To-Consumer Advertising Campaign

Digene Corp. (Gaithersburg, MD) has launched a magazine and television advertising campaign for its human papillomavirus (HPV) test. The 30-second TV ads began in mid-March in three cities: Atlanta, Baltimore, and Philadelphia. The magazine ads will be placed in 10 national magazines beginning with the April or May issues: *People, Ladies Home Journal, Redbook, O (Oprah), Family Circle, Woman's Day, First for Women, Cosmopolitan, Real Simple,* and *Parents*.

The ads will inform women that almost all cervical cancers are caused by HPV and that the Digene HPV test can help a woman's doctor reduce her chance of developing cervical cancer. The ads will direct women to a 1-800 number and Digene's Web site for more information.

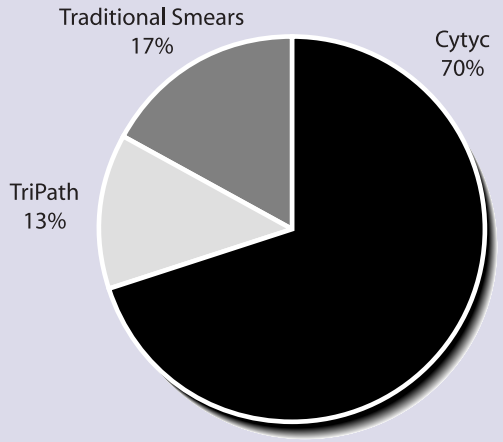
A Digene spokeswoman says the company has budgeted $3 million to $5 million for this initial campaign and will then evaluate the results and make a decision whether or not to expand it.

MonoGen Seeks FDA Clearance For New Liquid-Based Pap Test

More competition is coming to the lucrative liquid-based Pap testing market. MonoGen Inc. (Vernon Hills, IL) says it has completed clinical trials for its MonoPrep Pap test system and in December it filed a premarket approval application with the FDA.

MonoGen is a privately held company that is 47% owned by the venture capital firm Oxbow Equities (Montreal, Canada). Andre Denis, president of Oxbow, anticipates that MonoGen will begin commercialization of the MonoPrep system within the next 12 months.

Market Share for Pap Test Vendors, 2004



Source: *DTTR* estimates

Currently, 83% of the some 55 million Pap tests performed every year in the United States are prepared with liquid-based preparations. Cytyc's ThinPrep system dominates the market with an estimated 70% share, while TriPath's SurePath system has a 13% share, according to *DTTR* estimates.

Cytyc also dominates among the nation's largest laboratories *(see table below)*. Quest Diagnostics, which processes 13 million Pap tests per year, uses Cytyc as its primary vendor as does LabCorp, which processes nine million. In fact, 12 big labs with a combined 26.4 million in annual Pap testing volume each use Cytyc as their primary vendor, although TriPath has a minimal share at each company as well.

Pap Testing at 12 Big U.S. Lab Companies, 2004

	Annual Pap Volume	Conversion to Liquid Pap	Primary Vendor
Quest Diagnostics	13,000,000	87%	Cytyc
LabCorp	9,000,000	80%	Cytyc
AmeriPath	1,500,000	80%	Cytyc
JVHL	1,100,000	80%	Cytyc
LabOne	500,000	85%	Cytyc
PathNet Esoteric Lab	330,000	85%	Cytyc
DCL Medical Laboratories	275,000	75-85%	Cytyc
Sunrise Medical Labs	180,000	94%	Cytyc
Bio-Reference	150,000	70-80%	Cytyc
Westcliff Medical Labs	150,000	85%	Cytyc
Spectrum Laboratory	135,000	95%	Cytyc
SED Medical Labs	63,000	72%	Cytyc
Totals	26,383,000	80-85%	

Source: *DTTR* from companies

With 83% of the market already converted to either Cytyc or TriPath, MonoGen will have its work cut out for it when it comes to gaining share.

So how do you win market share from Cytyc and TriPath? "With a better mousetrap and with a strong distribution partner [i.e., Cardinal Health]," answers Denis. Will MonoGen use lower pricing to gain share? "That's a decision Cardinal will make," says Denis.

In November 2004, MonoGen signed a deal that gave Cardinal exclusive marketing and distribution rights in the United States for the MonoPrep products.

Industry sources expect MonoGen and Cardinal to introduce the MonoPrep instrument system and consumables at a much lower cost than Cytyc and TriPath. They tell *DTTR* that the system will include the ability to randomly load and process Gyn and non-Gyn specimens, and will have the ability to perform a broad base of molecular pathology testing because of a unique preservation solution that does interfere with those tests.

Out-of-the-Vial HPV Testing

Naturally, Pap testing laboratories will appreciate having a third liquid-based Pap test vendor to choose from, and pricing is almost certain to get more competitive. But the key to MonoGen's initial success may depend on out-of-the-vial HPV testing. Industry sources tell *DTTR* that MonoGen has completed clinical trails for out-of-the-vial HPV testing and included the results with its FDA application for MonoPrep.

Right now, Cytyc's ThinPrep is the only product approved for this; TriPath has been trying gain clearance for out-of-the-vial HPV testing for several years. Its inability to offer this claim on product labeling for SurePath has slowed TriPath's market share gains.

Targeting the Uninsured Population

DTTR hears that MonoGen may try to first penetrate the market by starting with the underserved uninsured women in the United States. It is in this population that a great deal of cervical cancer disease is found, according to Alan Kaye, president of the PathNet Esoteric Lab Institute (Van Nuys, CA), a clinical lab focused on women's health.

Kaye, who is also executive director of the National Cervical Cancer Coalition (Berkeley, CA), says that Cytyc and TriPath have begun to penetrate the uninsured market. However, they have had problems as the not-for-profit clinics and County and state family programs that manage these screenings often do not have the funds to provide the more expansive liquid-based Pap tests, he says.

PA Cytology Services Wins Alabama Contract at Cutthroat Price

Among the handful of states that have moved to liquid-based Pap testing has been Alabama, which recently awarded a one-year $750,000 contract, effective Jan. 18, 2005, to Pennsylvania Cytology Services (Monroeville, PA), a clinical lab that specializes in cytology. The contract mainly covers non-Medicaid, completely uninsured, poor women in the state's family planning program.

Pennsylvania Cytology Services won the contract at a rate of $13.95 per liquid Pap test using Cytyc's ThinPrep, with reimbursement of $35.95 per reflex HPV test for indeterminate results. These rates were challenged by competing labs, which thought they were too low to provide quality service and testing; however, the state of Alabama reviewed the contract and let it stand.

Labs Pay $9.75/Test for Cytyc and $7.91/Test for TriPath, Says G-2 Survey

The average lab pays $9.75 to Cytyc for its ThinPrep test and $7.91 for TriPath's SurePath, according to an exclusive national survey of 167 labs (115 hospitals, 31 independents, six pathology groups, six POLs, and nine other labs) conducted by Washington G-2 Reports in mid-March. The average price paid for traditional Pap test reagents and supplies was $1.91 and those labs sending their liquid-based Paps to a reference lab paid an average of $22.39.

The survey did not include data from the nation's three largest lab companies (Quest Diagnostics, LabCorp, or AmeriPath), which presumably pay substantially lower prices for their Pap testing supplies. The labs responding to the survey processed an average of 33,292 Pap tests per year. The 167 labs performed a total of 5.6 million Pap tests per year, of which 81% were converted to liquid-based Paps.

Summary Pricing Data for Pap Testing

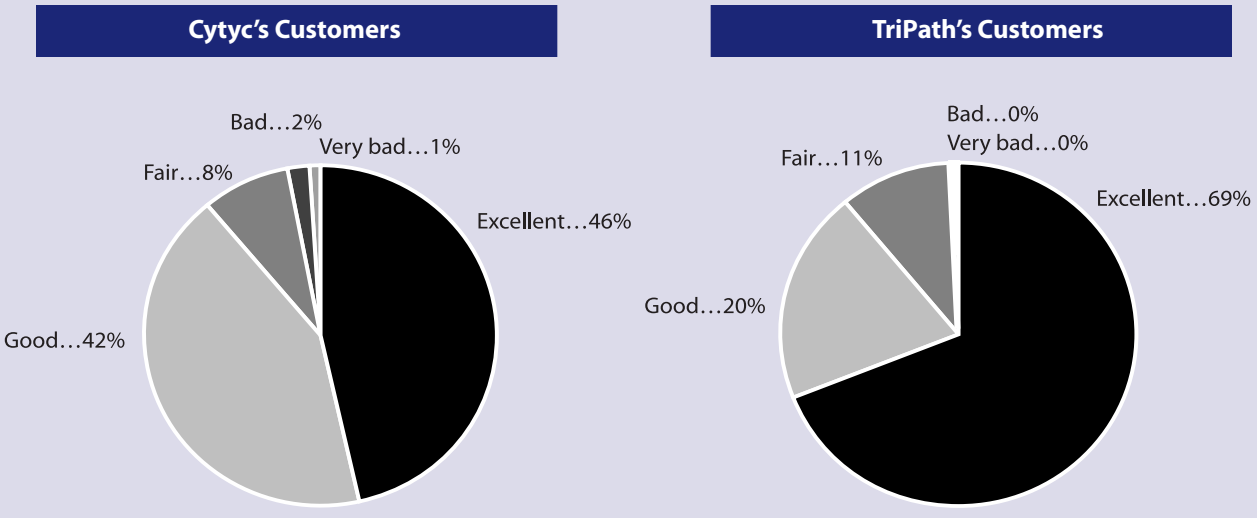
	Avg.	High	Median	Low
Cytyc's ThinPrep	$9.75	$20.00	$9.00	$5.62
TriPath's SurePath	7.91	16.79	7.00	5.00
Traditional Pap	1.91	4.00	1.60	0.34
Reference lab	22.39	33.75	23.00	14.00

Source: Washington G-2 Pap Testing Survey, March 2005

Sixty-five percent of labs cited Cytyc as their primary vendor for liquid-based Paps and 21% cited TriPath, while 4% said they still primarily perform traditional Pap tests and 10% said they send their Pap tests to a reference lab.

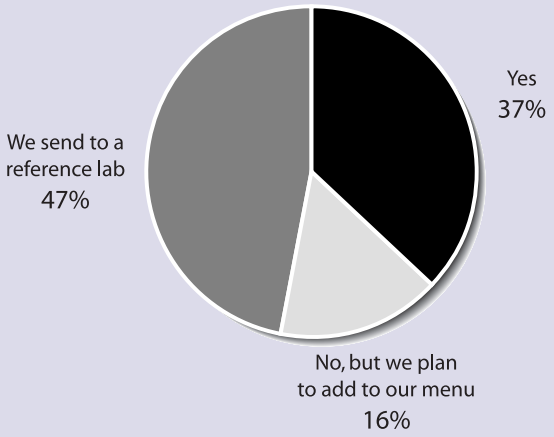
Of the 108 labs in the survey that listed Cytyc as their primary Pap test vendor, 89% said Cytyc's service was excellent or good, 8% said it was fair, and 3% called it bad or very bad. Of 35 TriPath customers, 89% said TriPath's service was excellent or good; 11% rated it fair; and none said it was bad or very bad.

How would you describe the quality of service provided by your primary liquid-based Pap testing vendor?



Source: Washington G-2 Pap Testing Survey, March 2005

Does your lab perform DNA-based HPV testing for inconclusive Pap tests?



Source: Washington G-2 Pap Testing Survey, March 2005

Thirty-seven percent of survey respondents said they perform HPV testing for inconclusive Pap tests, while 16% said they don't now, but plan to add HPV testing to their menu within one year. The remaining 47% said they said their HPV tests to a reference lab and have no immediate plans of bringing this test inhouse.

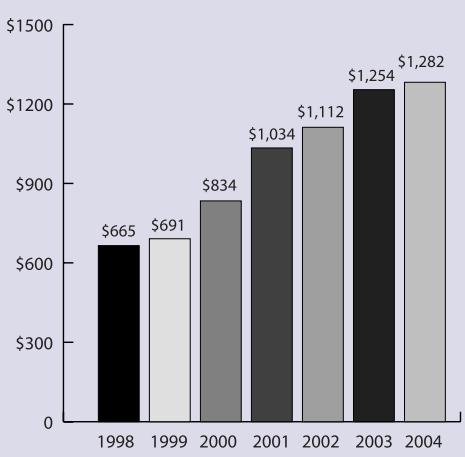
The Lucrative Pap Testing Market

The adoption of more expensive liquid-based Pap testing technologies, combined with positive changes in Medicare reimbursement and modest growth in the number of tests performed, have made Pap testing a very lucrative market for Cytyc, TriPath, and many of their lab customers.

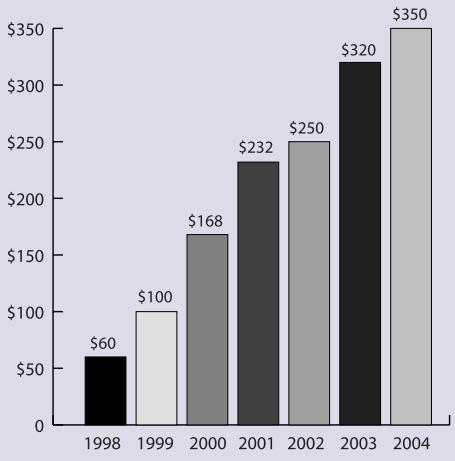
DTTR estimates that laboratory revenues from Pap testing (liquid-based and traditional) have doubled to $1.3 billion over the past six years in the United States. Over the same time frame, combined revenue at Cytyc and TriPath for liquid-based Pap testing supplies has grown from $60 million to $350 million.

However, with liquid-based Pap testing penetration now at 83%, growth is starting to slow down. There is also the risk that Medicare could cut its reimbursement rate (now at $28 for non-automated tests). Medicare beneficiaries account for only about two million Pap tests performed each year. However, the agency's coverage decisions and reimbursement rates set the standard that most managed care companies and indemnity plans follow.

U.S. Lab Service Revenues from Pap Testing *($ millions)*



Vendor Revenue from U.S. Liquid-Based Pap Testing Supply Sales *($ millions)*



Source: *DTTR*

▲ **Worldwide IVD Sales Rise 6%,** *from page 1*

Roche (Basel, Switzerland) remained the largest IVD company with a 22% market share. On a worldwide basis, Roche grew its diagnostics business by 8.7% (after adjustments for currency changes and divestitures) to 7.3 billion Swiss francs (US $6.3 billion).

Roche's fastest-growing business segment was molecular diagnostics, which grew 12% to 1.1 billion Swiss francs (US $913 million). Within the molecular diagnostics segment, Roche's Cobas AmpliScreen for blood screening grew fastest, up 32% to 277 million Swiss francs (US $229 million). Within the centralized diagnostics segment, Roche's Elecsys immunochemistry product line grew fastest, up 21% to 882 million Swiss francs (US $729 million).

After adjustments for divestitures, Roche Diagnostics grew its revenue in the U.S. market by 8% to an estimated $1.8 billion in 2004.

Top 15 IVD Manufacturers' Worldwide Revenue *($ millions)*

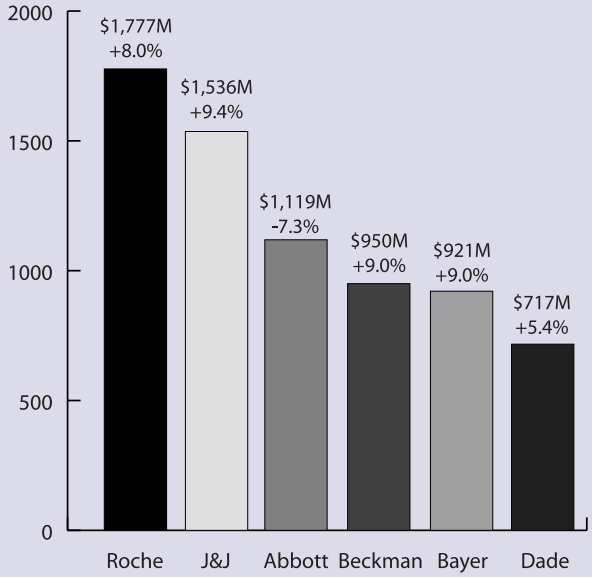
Company	Full-Year 2004 Revenue	Full-Year 2003 Revenue	Reported % Chg	Adjusted % Chg*	Market Share
Roche Diagnostics[1]	$6,277	$5,937	5.7%	8.7%	22%
Abbott Diagnostics[2]	3,378	3,040	11.1	-1.6	12
Johnson & Johnson	2,974	2,602	14.3	10.3	10
Bayer Diagnostics	2,643	2,587	2.2	6.9	9
Beckman Coulter[3]	1,722	1,541	11.7	9.1	6
Dade Behring	1,560	1,436	8.6	4.0	6
Becton Dickinson[4]	1,141	999	14.2	9.4	4
BioMerieux[5]	1,065	1,051	1.3	4.7	4
Sysmex[6]	725	629	15.2	NA	3
Olympus[7]	718	684	4.9	NA	3
Bio-Rad Labs[8]	576	515	12.0	6.3	2
Diagnostic Products	443	381	16.2	11.0	2
Cytyc Corp.[9]	330	303	8.9	8.5	1
Gen-Probe	270	207	30.2	30.0	1
Biosite	245	173	41.3	40.0	1
Top 15 total	24,066	22,086	9.0	6.3	85
Other IVD companies	4,247	3,898	9.0	6.3	15
Total IVD Market	$28,313	$25,983	9.0%	6.3%	100%

*Excludes effect of currency changes and acquisitions and divestitures

(1) Roche revenue excludes applied science segment. (2) Abbott's adjusted % growth includes impact of i-Stat and TheraSense acquisitions. (3) Beckman revenue excludes biomedical research segment (4) Becton Dickinson revenue includes diagnostic systems and flow cytometry. (5) BioMerieux revenue excludes industrial application sales. (6) Sysmex revenue is from company forecast for the fiscal year ending March 31, 2005. (7) Olympus' 2004 revenue is projected based on reported results for the nine months ended Dec. 31, 2004. (8) Bio-Rad revenue excludes life science segment. (9) Cytyc's revenue excludes sales from surgical products (i.e., Novacept).

Source: *DTTR* from company financial reports

U.S. Revenue for Six Leading IVD Vendors, 2004



Source: *DTTR* estimates and company reports

Abbott Diagnostics (Abbott Park, IL) saw its worldwide revenue fall by nearly 2% to $3.4 billion in 2004 (after adjustments). Abbott's revenue in the U.S. market fell by 7.3% to $1.1 billion. Its weakest area in the U.S. market was its core clinical diagnostics and reagents segment, which declined by 14% to $741 million; the company's blood glucose self-testing segment grew by 9% to $378.

Johnson & Johnson (New Brunswick, NJ), including Ortho-Clinical Diagnostics (OCD) and Lifescan, grew its worldwide revenue by 10.3%. J&J's revenue in the United States was up 9.4% to $1.5 billion, including $920 million, up 13%, at Lifescan and $616 million, up 5%, at OCD.

Bayer Diagnostics (Tarrytown, NY) grew its worldwide revenue by 6.9% to reach 1,975 euros (US $2.6 billion); revenue in the U.S. market grew by an estimated 9% to $921 million. Bayer's fastest-growing product line was its Advia Centaur immunoassay system, which grew by 19.1% for worldwide revenue of 441 million euros (US $592 million).

Beckman Coulter (Fullerton, CA) grew its worldwide clinical diagnostics business by 9.1% to $1.7 billion; sales in the United States increased by an estimated 9.1% to $950 million.

On a worldwide basis, **Dade Behring** (Deerfield Park, IL) grew by 4% (after adjustments) to $1.56 billion in 2004. Dade grew its revenue in the U.S. market by 5.4% to $717 million.

Cytyc Pays $160 Million For Proxima Therapeutics

Cytyc Corp. (Marlborough, MA) has acquired Proxima Therapeutics (Alpharetta, GA) for $160 million, plus the potential for additional payments based on sales of Proxima products over the next two years.

Proxima's lead product, the MammoSite Radiation Therapy System, is a single-use device for the treatment of breast cancer. Mammosite positions radiation sources directly into the post-lumpectomy site to optimize radiation treatment delivery and minimize damage to healthy tissue. The system reduces treatment time to five days compared to 30-35 days for traditional whole breast external beam radiation therapy.

Proxima's revenue from MammoSite increased 50% in 2004 to reach $12.6 million; revenue for 2005 is expected to grow to approximately $65 million. This means Cytyc is paying about 13 times last year's revenue ($160 million/$12.6 million=12.7) and 2.5 times projected revenue for 2005 ($160 million/$65 million=2.5 times).

IVD Stocks Drop 8%; Third Wave Slumps; OraSure Jumps

The 21 stocks in the G-2 Diagnostic Stock Index fell an unweighted average of 8% in the five weeks ended March 9, with five stocks up in price and 16 down. Year to date, the G-2 Index is off 4%, while the S&P 500 Index is unchanged and the Nasdaq is down 5%.

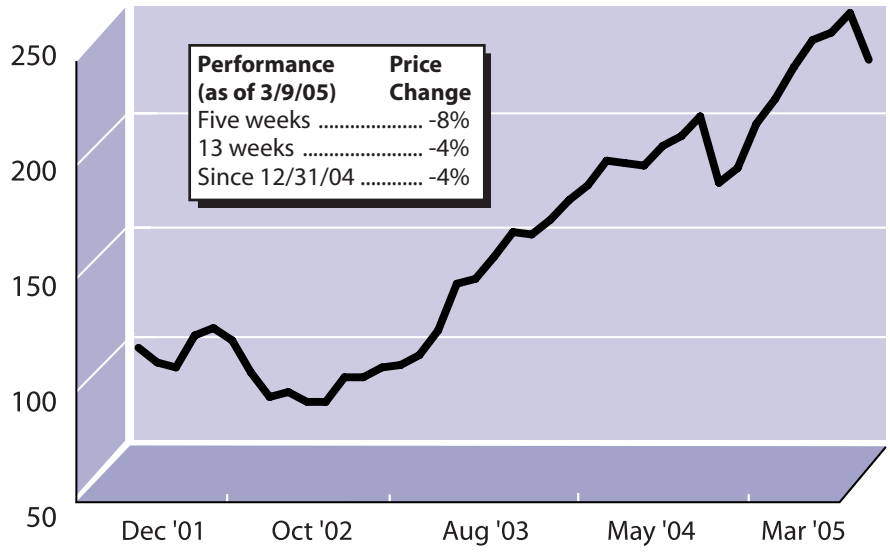
Third Wave Technologies (Madison, WI) fell 36% to $5.16 per share for a market value of $210 million. The company reported revenue of $46.5 million for 2004, up 28% from $36.3 million the previous year. However, investors were disappointed with the company's projections for revenue of between $33 million and $41 million for this year.

OraSure Technologies (Bethlehem, PA) was up 13% to $6.70 per share for a market value of $300 million. The company, which makes rapid HIV tests, was lifted by two studies published in the Feb. 10 edition of the *New England Journal of Medicine* that found expanding routine HIV screening would be a cost-effective way to reduce transmission and improve public health.

Testing in areas where there's low prevalence of the virus that causes AIDS is affordable and prolongs the life of people carrying HIV without knowing it, the studies found. The studies — one from Duke University and the Veterans Affairs Palo Alto Health Care System, and the other from researchers at Harvard and Yale — were conducted independently of each other but show similar results.

"While the Centers for Disease Control and Prevention's guidelines are that routine screenings are effective in settings where there is a 1 percent or above prevalence of disease, our analysis showed that such screening at much lower prevalence levels would provide important benefits," said Gillian Sanders, Ph.D., lead author of the Duke and Palo Alto report, in a statement.

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.

% price change, Year-to-Date as of 3/9/05

UP	Price	% Chg
Abbott Labs	45.90	1%
Dade Behring	62.32	7%
Immucor	31.96	3%
Johnson & Johnson	67.76	2%
OraSure	6.70	13%
DOWN		
Abaxis	10.85	-17%
Affymetrix	40.78	-5
Beckman Coulter	69.32	-1%
Becton Dickinson	58.05	-2%
Bio Rad	48.20	-18%
Biosite	53.68	-14%
Cholestech	10.48	-21%
Cytyc	21.94	-14%
Diagnostic Products	47.82	-13%
Digene	22.54	-14%
Gen-Probe	47.80	-4%
Inverness Medical	22.35	-12%
Meridian	15.84	-10%
Quidel	3.92	-15%
Third Wave	5.16	-36%
Ventana	69.34	-1%

G-2 Insider

Tidbits from our Pap Testing Survey. . .

"It's a good system [liquid-based Pap testing], but it's expensive," was one of the typical comments that lab directors and managers offered on Washington G-2's Pap Testing Survey forms (*see pp. 7-8*). "Basing the price of reagents on the percentage conversion to liquid-based procedures should not be tolerated. Volume of purchase should be the criteria for discount," said a hospital lab director from Kansas.

"The battle between ThinPrep and SurePath has reduced Pap smears to a soda-like commodity. . . .Patient care has ceased to be an issue as marketing has focused on physicians and patients to create the brand demand," commented an operations manager at a pathology group.

A cytopathology manager from Colorado noted: "The business of Pap testing has become increasingly competitive. Commercial laboratories are aggressively marketing their services, making it difficult for hospital laboratories to maintain sufficient volumes."

More than one survey participant also said that, while reflex HPV testing for ASCUS Pap tests was being widely used, the DNA Pap screening (HPV plus Pap test) was not catching on. On the other hand, a number of labs did say that they had plans to begin using new automated imaging systems from Cytyc or TriPath.

Labs also voiced strong opposition to government plans to begin enforcing proficiency testing requirements for cytotechnologists as spelled out in the 1992 CLIA rules. "The new proficiency testing regulations from the federal government will put many of the small pathology practices out of business due to cost; these businesses will end up sending their Paps to the large labs, and patient care will thereby be adversely affected," said a medical director from a hospital lab in Texas.

Company References

Correlogic 301-214-4030

Cytyc Corp. 978-263-8000

Digene 301-944-7000

Matritech 617-928-0820

MonoGen 847-573-6700

OraSure 503-641-6115

Third Wave 608-273-8933

TriPath 336-222-9707

Diagnostic Testing & Technology Report (ISSN 1531-3786) is published by Washington G-2 Reports, 3 Park Avenue, 30th Floor, New York, NY 10016-5902. Tel: 212-244-0360. Fax: 212-564-0465. Order line: 212-629-3679. Website: *www.g2reports.com*

Jondavid Klipp, Managing Editor; Dennis Weissman, Executive Editor; Janice Prescott, Sr. Production Editor; Perry Patterson, Vice President and Group Publisher.

Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 212-244-0360, ext. 2.