Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

Is The FDA Putting The Hammer Down On Home Brews?

Recent actions by the FDA suggest that the agency is taking a more active role in requiring premarket clearance for home-brew tests that have components, including software, that could be considered medical devices.

And, if all else fails, the FDA can always fall back on the Federal Food, Drug, and Cosmetic Act, which states that the agency has regulatory authority for any test that is "intended for a use which is of substantial importance in preventing impairment of human health" or if it "presents a potential unreasonable risk of illness or injury."

It should be no surprise that some home-brew tests have captured the FDA's attention, given the way their manufacturers are promoting them through press releases, newspaper articles, direct sales forces, and in some cases, TV commercials.

Most recently, the FDA has determined that a component of Exact Science's PreGen-Plus, a DNA-based test for colorectal cancer, is a medical device that needs premarket clearance. And the agency has questioned if the software used by Genomic Health for its Oncotype DX breast cancer test needs premarket clearance.

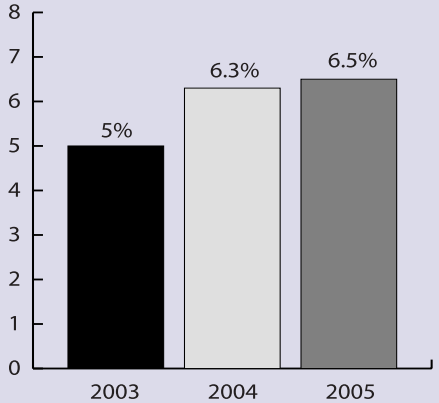
For more information on the regulatory status of tests marketed by Exact Sciences, Genomic Health, and Correlogic Systems, see *Inside the Diagnostics Industry*, pp. 5-7.

Worldwide IVD Sales Up 6.5% To $30 Billion

Worldwide IVD sales grew by 6.5% (excluding the effect of currency changes and acquisitions) to $29.7 billion in 2005, 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 6.5% growth rate for 2005 marks a small acceleration from the 6.3% growth recorded in 2004.

➥ *p. 2*

Annual Worldwide IVD Market Growth



Source: *DTTR* estimates

▲ **Worldwide IVD Sales Up 6.5% to $30 Billion,** *from page 1*

The fastest-growing IVD companies last year were Biosite, up 17%; Gen-Probe, up 13%; and Cytyc Corp., up 10%.

Among the largest IVD companies, **Johnson & Johnson** (New Brunswick, NJ), including Ortho-Clinical Diagnostics (OCD) and LifeScan, grew the fastest. Its worldwide revenue increased by 11% to $3.3 billion. J&J's blood glucose monitoring business, LifeScan, grew by 12% to $1.9 billion. OCD's revenue was up 10% to $1.4 billion. A company spokeswoman says OCD's growth was due to strong sales from: 1) Vitros ECiQ, an automated immunoassay system; 2) Vitros 5,1 FS, a consolidated chemistry-immunoassay analyzer; and 3) AutoVue Innova, an automated blood bank analyzer.

The next fastest-growing big IVD company was **Bayer Diagnostics** (Tarrytown, NY), which increased its worldwide revenue by 8% to $2.6 billion. Bayer's Advia Centaur immunoassay system business grew by 16% to $615 million; Ascensia blood glucose products were up 12% to $842 million.

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

Company	Full-Year 2005 Revenue	Full-Year 2004 Revenue	Reported % Chg	Adjusted % Chg*	Market Share
Roche Diagnostics[1]	$5,952	$5,669	5.0%	4.0%	20%
Abbott Diagnostics[2]	3,756	3,378	11.2	7.3	13
Johnson & Johnson	3,317	2,974	11.5	11.0	11
Bayer Diagnostics	2,588	2,376	8.9	8.0	9
Beckman Coulter	2,444	2,408	1.5	0.6	8
Dade Behring	1,658	1,560	6.3	5.9	6
Becton Dickinson[3]	1,254	1,141	9.9	7.8	4
BioMerieux[4]	1,039	974	6.6	5.3	4
Sysmex[5]	741	655	13.1	NA	2
Bio-Rad Labs[6]	618	576	7.3	5.9	2
Diagnostic Products	481	447	7.7	5.7	2
Olympus[7]	402	354	13.6	NA	1
Cytyc Corp.[8]	362	330	9.6	9.5	1
Gen-Probe	306	270	13.4	13.0	1
Biosite	288	245	17.5	17.0	1
Top 15 total	25,205	23,357	7.9	6.5	85
Other IVD companies	4,448	4,196	6.0	6.0	15
Total IVD Market	$29,653	$27,553	7.6%	6.4%	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) Becton Dickinson revenue includes diagnostic systems and flow cytometry. (4) BioMerieux revenue excludes industrial application sales. (5) Sysmex's 2005 revenue is from company forecast for the fiscal year ending March 31, 2006. (6) Bio-Rad revenue excludes life science segment. (7) Olympus' 2005 revenue is from company forecast for the fiscal year ending March 31, 2006. (8) Cytyc's revenue is for diagnostic products only. Source: *DTTR* from company financial reports

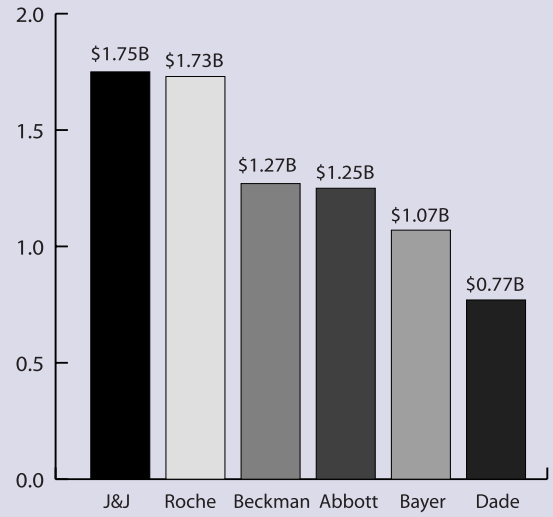
J&J Now Top U.S. Diagnostics Manufacturer

Among the six largest IVD companies, J&J grew the fastest in the United States in 2005, with a 14% increase in revenue to $1.75 billion. The growth pushed J&J ahead of Roche Diagnostics to make it the largest IVD company in the United States. Roche saw its U.S. revenue decline by 2% to $1.73 billion (excluding its applied science unit).

Bayer was next fastest growing in 2005 with U.S. revenue of $1.07 billion, up 8%. Dade Behring also posted strong growth, up 7% to $766 million. Led by strong blood glucose test sales, Abbott's U.S revenue grew by 6.5% (after adjustments for acquisitions) to $1.25 billion.

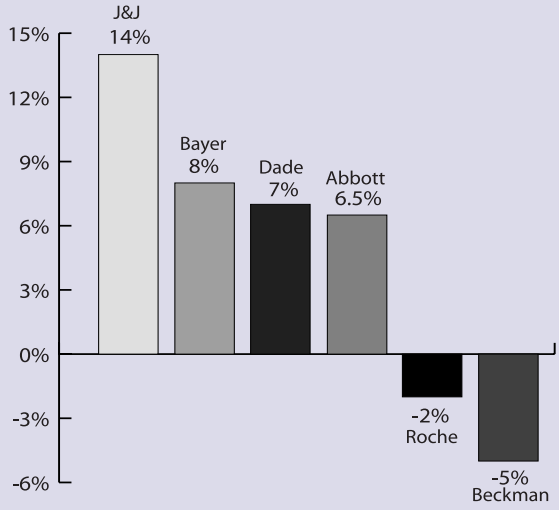
Finally, Beckman Coulter reported a 5% drop in U.S. revenue last year to $1.27 billion.

U.S. Revenue for Six Largest IVD Vendors, 2005



*All figures adjusted for currency changes and acquisitions

U.S. Revenue Change for Six Largest IVD Vendors, 2005*



Source: *DTTR* from company reports

Trinity Jumps In Race To Get HIV Test On Drugstore Counters

Trinity Biotech (Dublin, Ireland) has announced that it has written to the FDA requesting a meeting to discuss the conditions under which the FDA might grant marketing clearance for over-the-counter (OTC) sale of the company's UniGold HIV fingerstick blood test. In addition, Trinity says it presented its case for OTC sale of the test at a meeting of the Blood Products Advisory Committee (BPAC) of the FDA in Washington on March 10.

Trinity says studies of its HIV test in 9,000 patients showed the device had 100% accuracy in detecting a true positive result and 99.7% ability to detect a true negative result.

Trinity's UniGold HIV test is one of only two products which are FDA approved and CLIA waived. The other is the OraQuick Advance saliva test made by OraSure Technologies (Bethlehem, PA). OraSure has been in talks with the FDA regarding

OTC sale of its test for the past six months and was also at the BPAC meeting. OraSure says the meeting provided clarification of the regulatory pathway for an OTC HIV test and that it intends to begin these required clinical studies as soon as possible.

LabNow Prepares Launch of Point-Of-Care HIV Monitoring Test

In sub-Saharan Africa, an estimated 25.8 million people were living with HIV at the end of 2005 and approximately 3.1 million new infections occur per year, according to the 2005 UNAIDS/ WHO AIDS Epidemic Update.

LabNow Inc. (Austin, TX) is aiming to launch its novel CD4Now test system early next year, Joe Skraba, vice president of business development, tells *DTTR*. He says the system will be commercially available first in Africa. FDA clearance and roll-out in the United States is expected in the first quarter of 2007.

The CD4Now system is a simple two-step blood test that measures the number of CD4 lymphocytes and CD4 percentage in fingerstick whole blood within 10 minutes. CD4 count is a key indicator of the progression of HIV/AIDS and is used by clinicians to determine the course of antiretroviral drug treatment. LabNow's CD4 test has been shown to statistically correlate ($r^2 = 0.96$) with flow cytometry CD4 counts.

The system is composed of a toaster-sized analyzer and assay-specific microfluidics sensors (aka, BioChips). Skraba says the analyzer will be priced at roughly $5,000. In comparison, prices for flow cytometers, the current gold standard method for counting CD4 cells, begin at about $30,000. He anticipates that the CD4 BioChips will be priced at one-third to one-half of traditional CD4 tests, which cost upward of $40 each, depending on test volumes.

Skraba says the CD4Now test can be performed by minimally trained technicians. "All the technician needs to be able to do is get a drop of blood from the patient onto a BioChip and insert the biochip into the analyzer. Everything else is automated," according to Skraba. The system also has the advantage of portability, he adds. No blood needs to be transported to central labs, and the device, which weighs less than five pounds, can be run on batteries or wall power.

LabNow at a Glance

Headquarters:	Austin, Texas
Chief executive:	Richard Hawkins
Chief scientific officer:	J. Lawrence Fox, Ph.D.
Employees:	20
Funding:	$14M from George Soros, Austin Ventures, and individual investors

Source: LabNow

LabNow was founded by chief executive Richard Hawkins, Skraba, and Trey Herschap, vice-president of product marketing, in February 2004. Later that year, the company raised $14 million; half from billionaire George Soros and the remainder from Austin Ventures and individual investors.

The CD4Now system is based on technology developed at the University of Texas at Austin by John McDevitt, Ph.D. Through the agreement that licensed McDevitt's technology, the University of Texas owns 10.5% of LabNow and will collect royalties from the sale of the analyzers and tests. However, McDevitt says the University of Texas will take no royalties from sales to resource-poor settings like Africa.

FDA Guidance On ASRs Is On Its Way

New diagnostic technologies such as DNA chips and complex software programs for analyzing lab test results are creating confusion as to the regulatory definition of a home-brew test (note: the politically correct term is "laboratory developed" test). The confusion could result in several important lab tests (eg., PreGen-Plus and Oncotype DX) being taken off the market and has prevented another (OvaCheck) from getting off the ground.

"We are working on a guidance to clarify the confusion which has developed around the ASR rule. We are not working on regulations themselves at this time. The guidance is a high priority work item, but it is not clear to me what the timeline for this will be, Steven Gutman, M.D., director of the office of IVD device evaluation and safety at the FDA, tells *DTTR*.

Meanwhile, several niche reference labs with one-test menus are sweating it out. Here is a snapshot of what's happening at Exact Sciences, Genomic Health, and Correlogic Systems.

FDA Says LabCorp/Exact Sciences DNA Test Needs Approval

In January, LabCorp (Burlington, NC) received a letter from the FDA stating that PreGen-Plus, a DNA-based colorectal cancer test developed by Exact Sciences (Marlborough, MA), is subject to regulation and will require a premarket submission as a medical device. "This was a surprise to us," Don Hardison, chief executive of Exact Sciences, told investors on a January 19 conference call. Despite the FDA's letter, LabCorp is continuing to market the test.

Exact developed the Pregen-Plus test and licensed it to LabCorp in June 2002 under an exclusive agreement. LabCorp introduced the test to the clinical market in August 2003 as a home brew. LabCorp paid $15 million to Exact for the initial agreement and another $15 million when the test was made commercially available. In addition, LabCorp has committed to paying another $45 million to Exact if the test reaches certain sales targets, clinical guideline acceptance, and Medicare coverage.

Initially, LabCorp tried marketing the test at a list price of $795. But LabCorp cut the price to $495 in mid-2005 in an effort to stimulate demand.

Meanwhile, Hardison says LabCorp has requested a meeting with Steven Gutman, M.D., director of the office of IVD device evaluation and safety at the FDA, to discuss the "appropriate regulatory path" for the test. This is an issue for which the FDA seems to have already made its mind up, observes *DTTR*.

FDA Actions in the Home-Brew Testing Market

Company	Assay	Date of first FDA inquiry	Current Status
Roche	AmpliChip CYP450	July 2003	Cleared by FDA in Jan. 2005
Correlogic	OvaCheck	March 2004	Off market; needs PMA
Exact Sciences	PreGen-Plus	mid-2005	Needs PMA, but still on market
Genomic Health	Oncotype DX	Jan. 2006	Still on market; regulatory status not determined yet

Source: *DTTR*

The FDA's attention to PreGen-Plus was captured during Exact's efforts to gain Medicare coverage for the test last year. Before rendering a coverage decision, the Centers for Medicare and Medicaid Services asked Exact for clarification on the regulatory status of PreGen-Plus. Exact went to the FDA for the answers, and those meetings led to the agency's decision that the test needs premarket approval.

In particular, Hardison said the FDA is interested in the Effipure sample preparation reagents that are used to extract minute levels of mutated DNA for the PreGen-Plus test. Exact sells Effipure reagents on an analyte-specific-reagent (ASR) basis to LabCorp.

In addition to throwing a monkey wrench into Exact and LabCorp's hopes for a positive Medicare coverage decision, the FDA's opinion is also likely to sidetrack efforts to get PreGen-Plus recommended as a standard of care by various cancer groups like the American Cancer Society.

When questioned why Exact hasn't sought to bring PreGen-Plus through the FDA's 510K clearance process, Hardison told conference-call listeners: 1) he believes the test is properly categorized as a home brew; 2) the testing procedure is complex and would not be easy to put into kit form; and 3) the sensitivity of the test (currently about 60%) is in the process of being improved.

Meanwhile, *DTTR* notes that without Medicare coverage or standard-of-care guidelines, PreGen-Plus has struggled in the marketplace. Last year, Exact reported a net loss of $14.3 million on revenue of only $4.3 million from 4,000 accessions. Since being founded in 1995, the company has accumulated net losses of about $150 million.

Exact Sciences at a Glance *($000)*

	2005	2004
Revenue	$4,250	$4,935
Accessions	4,000	1,600
Net loss	-14,250	-18,523
Cash & securities	34,100	50,280

Source: Exact Sciences

Gutman would not comment to *DTTR* on the current status of his agency's discussions with LabCorp and Exact. But given the FDA's recent activity in questioning the status of home-brew tests (e.g. Correlogics' OvaCheck, Roche's AmpliChip, Genomic Health's Oncotype DX, etc.), *DTTR* asked if the FDA was taking a stricter regulatory stance on home-brew testing. "The FDA has not changed its position with regard to either ASRs or home brews and so actions being considered relate to conformance to existing regulations," he answered.

FDA Questions Genomic Health's Oncotype DX Test

On January 23, Genomic Health (Redwood City, CA) received a letter from the FDA asking for a meeting to discuss the nature and regulatory status of its breast cancer test, Oncotype DX. The test evaluates a panel of 21 genes and uses a proprietary software program to quantify the risk of breast cancer recurrence and predicts the likelihood of response to chemotherapy for early-stage patients.

The FDA is probably most interested in the software used with the Oncotype DX test and could conclude that the software is a device for which premarket approval is needed.

"We invite you to meet with us at your earliest convenience to discuss the nature and appropriate regulatory status of your technology, and the least bur-

densome ways that Genomic Health may fulfill any premarket review requirements that may apply," read the letter from the FDA's Gutman.

A spokeswoman from Genomic Health said the company was not sure what triggered the FDA's interest in Oncotype DX and would not comment on when it would be meeting with the agency.

Genomic Health has been marketing Oncotype DX as a home-brew test for the past two years. The company employs 30 sales reps who market the test to oncologists at a list price of $3,460. The test is performed at the company's CLIA-certified laboratory in northern California. To date, more than 2,400 physicians have ordered the test at least once, and National Heritage Insurance Company, which administers Medicare programs in California, established a coverage policy for the test effective February 27.

Correlogic's OvaCheck Remains Out of the Market

An ominous sign for Genomic Health may be the ongoing struggle that Correlogic Systems (Bethesda, MD) has had in bringing its OvaCheck test for ovarian cancer to the market. The company and its two distribution partners, Quest Diagnostics and LabCorp, had hoped to bring OvaCheck to the clinical market as a home-brew test in early 2004. However, a letter from the FDA that questioned whether premarket clearance was needed first put the kibosh on those plans.

Then after several months of discussion and at least one face-to-face meeting, the FDA's Gutman ruled that the software used to analyze blood protein patterns for the OvaCheck test was subject to FDA regulation.

In a July 12, 2004, letter to Correlogic, Gutman explained that the FDA has recognized the skill and expertise of CLIA-regulated high-complexity laboratories that use reagents in test procedures and analyses of their own development. He said that the FDA has no plans to regulate the reference lab activities associated with OvaCheck testing at Correlogic, LabCorp, or Quest.

However, Gutman said the software for OvaCheck is subject to premarket approval because these components are "intended for use in the diagnosis of disease" and are therefore "devices."

In response, Correlogic moved the software for OvaCheck out of the laboratories at LabCorp and Quest and brought it in-house. But this still hasn't resolved the issue, and the test has remained off the market. Peter Levine, president of Correlogic, tells *DTTR* that the company remains in discussion with FDA, but declined further comment.

AmpliChip CYP450 Cleared by FDA, But Market Adoption Is Slow

Roche's AmpliChip CYP450 made the headlines in January 2005 when it became the first microarray for in vitro diagnostic use approved by the FDA. Roche, which manufactures the DNA chip, had initially sought to introduce the test as an ASR in early 2003. But the product was removed from the market in mid-2003 after the FDA determined premarket clearance was necessary. But in a matter of months, AmpliChip CYP450 gained FDA clearance, although clinician adoption rates for the test have been disappointing.

Semen-Based Test For Prostate Cancer Under Development

Australian-based Proteome Systems Ltd. and Egenix Inc. (Millbrook, NY) have signed an agreement to co-develop a semen-based immunoassay for prostate cancer and are aiming to have an ASR-version on the market within one to two years, Donald Fresne, chief executive of Egenix, tells *DTTR*.

The test looks for a complex protein, called human carcinoma antigen (HCA), which is patented by Egenix. HCA in the blood can signal the presence of cancer, but it does not specify where the cancer exists. Because the prostate's function is to secrete fluid into semen, HCA is found in much larger concentrations in semen produced by cancerous prostates and is therefore expected to be a highly specific marker.

Initial data testing HCA in semen as a marker for prostate cancer was presented at an American Urology Association in May 2004. In a cohort of 84 patients (nine confirmed cancers and 75 non-cancers), the sensitivity of the semen test was 100% and the false positive rate was 17%.

In comparison, the traditional PSA blood test for prostate cancer has a false positive rate estimated at up to 75%. This means that many men who have false positive tests for prostate cancer undergo unnecessary biopsies.

Proteome and Egenix will initially work together to optimize the detection of HCA in semen of prostate cancer patients. This initial project will be fully funded by Egenix. The two companies will then share the rights for further development and commercialization of the test.

Fresne believes the initial price for the reagents will be more than $50 per test, although he expects the price to drop after the test is cleared by the FDA in kit form. Initially, Fresne expects the test to be used as a reflex test for indeterminate PSA tests. He estimates that the potential market for the HCA test could be up to $1.5 billion per year in the U.S. market.

Egenix president Jedd Levine, M.D., says the company initially wondered whether men would object to providing semen for the test. "But it's common to look in organ secretions for signs of cancer in that organ ... and most men would willingly provide a semen specimen to potentially avoid a painful needle biopsy," he notes.

Finally, Fresne notes that the HCA marker appears in other cancers as well. Other potential HCA-based tests that Egenix may develop include blood tests for lung, ovarian, and bladder cancer, he says.

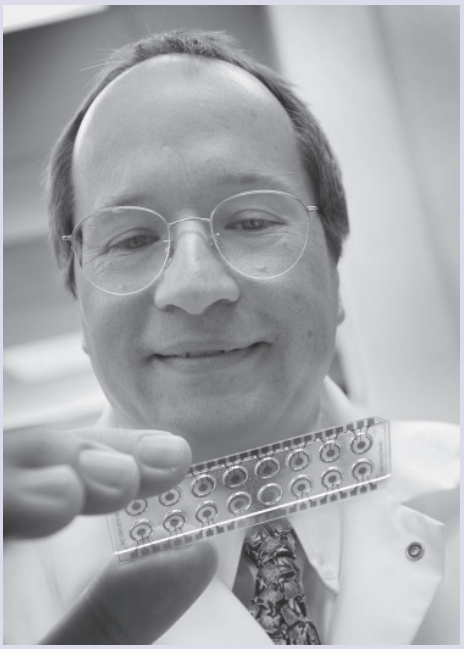
DNA Chips Show Promise For Rapid Urinary Tract Infection Testing

A clinical study published in the February 2006 issue of the *Journal of Clinical Microbiology* has shown that DNA chips developed using technology from GeneFluidics (Monterey Park, CA) can quantitatively detect bacterial pathogens in urine samples in about 45 minutes. This compares with today's culture-based methods, which have a turnaround time of two days.

The study, conducted by UCLA and the Veterans Affairs Greater Los Angeles Healthcare System, lays the foundation for a point-of-care-testing device for rapid diagnosis of urinary tract infections, according to Vincent Gau, M.D., founder and chief executive of GeneFluidics.

Urinary tract infections (UTIs) account for about eight million doctor's visits per year. A rapid UTI test would allow physicians to prescribe a targeted antibiotic treatment in one office visit. Today, physicians must decide whether to prescribe antibiotics, and if so which type, before receiving urine-culture test results.

Led by Joseph Liao, M.D., the researchers designed DNA probes against the most common UTI-causing pathogens and layered them on GeneFluidics' electrochemical DNA biosensors. Urine specimens directly applied to the chips were then analyzed by GeneFluidics' multi-channel reader instrument, which measured the electrochemical signal. Study results showed that the GeneFluidics/UCLA method correctly identified the infection-causing gram negative bacteria in 98% of the 78 clinical UTI samples tested.



David Haake, M.D., from the Geffen School of Medicine at UCLA, holds a "urocartridge."

GeneFluidics currently has a manual UTI detection system on the U.S. market that is being distributed by Fisher Scientific. Gau says that the company is working to integrate the biosensors into microfluidic cartridges (aka, urocartridges) and build a new, automated instrument. He expects the rapid UTI test to become commercially available in the next two to three years, with limited sales of beta products over the next year or so.

Gau is hesitant to provide exact-cost estimates, because final product specifications and appropriate reimbursement schedules are not yet known, but he expects that the urocartridges will be comparably priced to the cost of urine culture including labor. Medicare reimbursement for culture-based UTI testing currently ranges from $8 to $22, depending on whether the initial culture is positive and requires further analysis; managed care plans typically reimburse $12 to $40 per test.

GeneFluidics was formed in 2000 by Gau and the company's chairman, Chih-Ming Ho, Ph.D. The company's largest source of funding to date has been government grants, including a $5.6 million grant from the National Institutes of Health.

LabCorp Inks Exclusive Deal For Yale's Ovarian Cancer Test

LabCorp has signed an exclusive deal with Yale University to commercialize a blood test for epithelial ovarian cancer (EOC), the fourth-most common cancer that affects women in the United States.

Pam Sherry, spokeswoman for LabCorp, says the test will require additional clinical studies before it is ready for commercialization. Yale will receive signing, milestone,

Epithelial ovarian cancer affects about 25,000 women each year in the United States, with more than 16,000 dying from it.

and royalty fees for the test. Additional terms of the agreement weren't disclosed.

The Yale technology for the test is based on four serum proteins—leptin, prolactin, osteopontin, and insulin-like growth factor-II—associated with cancer. Each marker is analyzed using a routine ELISA assay, and the results are evaluated using a score system.

Research, led by Gil Mor, M.D., associate professor of obstetrics, gynecology, and reproductive sciences at the Yale School of Medicine, was published in the May 10, 2005, issue of *Proceedings of the National Academies of Sciences (PNAS).* The study involved 206 women, including 24 patients with early-stage and 76 with later-stage EOC.

The study found that if the levels of two or more of the four protein markers in a patient fall within a certain warning area, the test will predict that she has ovarian cancer. Overall, the test was found to exhibit the following qualities: 95% sensitivity; 95% positive predictive value; 95% specificity; and 94% negative predictive value.

The researchers are now investigating whether the markers are specific to EOC or if they can detect other cancers as well. The inclusion of other protein markers that may improve the sensitivity and specificity of the test is also being evaluated.

Third Wave Expects Point-Of-Care Molecular System By Year's End

The Japanese firms Shimadzu Corp. and Toppan Printing Co. Ltd. have signed a deal with Third Wave Technologies (Madison, WI) for the development and commercialization of a point-of-care instrument that could bring molecular diagnostics to the doctor's office. The companies anticipate commercializing a research-use-only (RUO) version of the instrument before the end of 2006.

The new instrument is roughly the size of a desktop computer and is expected to be the world's first fully automated system for nucleic acid analysis that can easily be used at the point of care. It is capable of analyzing a patient's DNA for specific gene sequences from a drop of whole blood in approximately 90 minutes.

Shimadzu and Toppan developed the instrument in partnership with Yusuke Nakamura, M.D., Ph.D., of the RIKEN Institute/University of Tokyo. It employs Nakamura's novel polymerase chain reaction (PCR) multiplexing technology, Shimadzu's AmpDirect reagents for performing PCR on whole blood, and Toppan's consumable chip platform.

Under the agreement, the companies will first apply Third Wave's Invader chemistry to the instrument for detection of variations in cytochrome P450 genes that can cause adverse drug reactions.

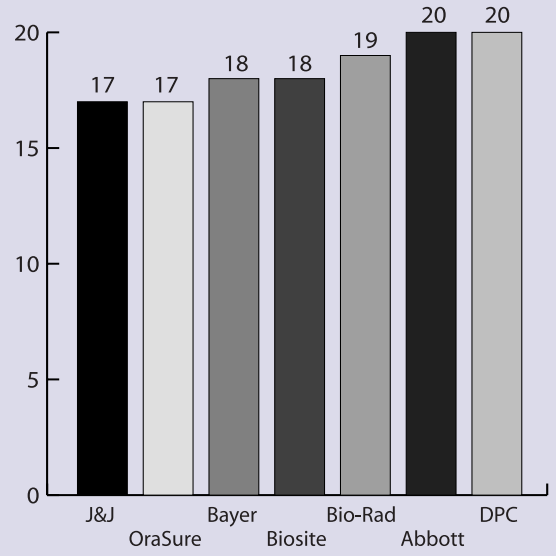
Third Wave has exclusive marketing rights for the instrument in the United States, Canada, and Europe, and will determine if FDA clearance or approval is required prior to commercialization in the United States. Shimadzu and Toppan have exclusive marketing rights for the rest of the world.

IVD Stocks Up 1%; Digene Jumps 28%; Affymetrix Slumps 20%

The 22 stocks in the G-2 Diagnostic Stock Index rose by 1% in the five weeks ended March, 10, 2006, with 10 stocks up in price and 12 down. Year to date, the G-2 Index is up 7%, compared with a 3% gain each for the S&P 500 Index and Nasdaq.

Digene Corp. (Gaithersburg, MD) jumped 28% to $41.73 per share for a market cap of $941 million. For the three months ended Dec. 31, 2006, Digene reported that total revenue increased 38% to $37.1 million; worldwide human papillomavirus (HPV) test revenue grew 45% to $32.3 million; and U.S. HPV test revenue increased 56% to $26.9 million.

IVD Company P/E Ratios

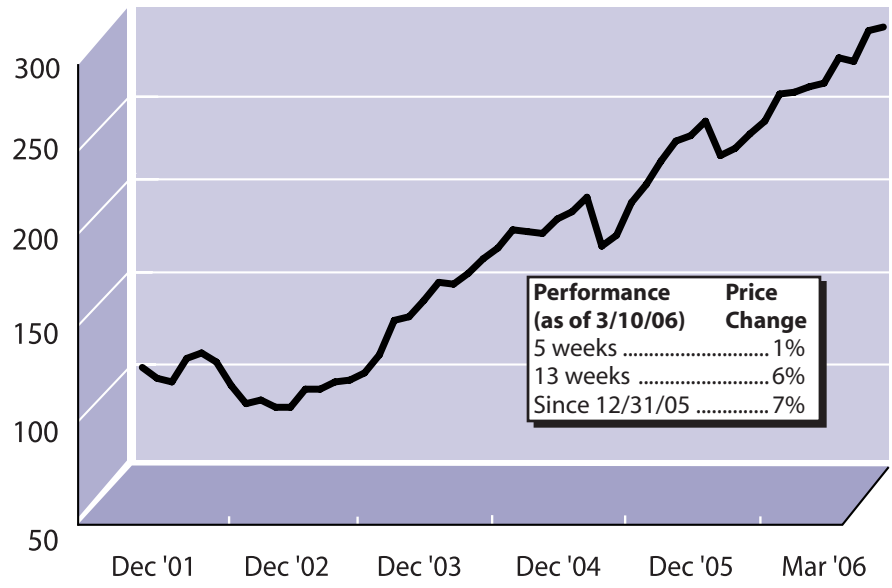


Source: *DTTR*

Affymetrix (Santa Clara, CA) fell 20% to $30.39 per share for a market cap of $1.7 billion. Much of the decline came after the company's chief financial officer, Gregory Schiffman, told the Citigroup 2006 Healthcare Conference in Washington, D.C., on February 28 that overall demand for its DNA chips has temporarily slowed.

Meanwhile, an analysis of the P/E ratios of IVD companies shows that **Johnson & Johnson** and **OraSure Technologies**—each has a P/E ratio of 17—are currently the least expensive stocks. Other IVD companies with a P/E ratio of 20 or less include: **Bayer** and **Biosite**, each at 18; **Bio-Rad** at 19; and **Abbott Labs** and **Diagnostic Products Corp. (DPC)**, each at 20.

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, 5 weeks ended 3/10/05

UP	Price	% Chg
Abaxis	$20.89	6%
Abbott Labs	43.92	4
Biosite	51.46	4
Cholestech	11.61	7
Cytyc	29.65	3
Digene	41.73	28
Gen-Probe	51.93	8
Johnson & Johnson	59.04	2
Quidel	11.19	12
Third Wave	3.30	2
DOWN		
Affymetrix	30.39	-20
Bayer	39.14	-5
Beckman Coulter	53.47	-10
Becton Dickinson	62.88	-1
Bio-Rad	58.99	-11
Dade	35.63	-11
Diagnostic Products	45.45	-10
Immucor	28.90	-4
Inverness Medical	25.05	-5
Meridian	21.73	-10
OraSure	10.00	-13
Ventana	37.41	-6

G-2 Insider

Move over Cytyc and TriPath: MonoGen Inc. (Vernon Hills, IL) just received FDA clearance to market its liquid-based MonoPrep Pap test. Roughly 90% of the some 60 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 20% share, according *DTTR* estimates.

But with 90% 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.

MonoGen is a privately held company that is 46% owned by the venture capital firm Oxbow Equities (Montreal, Canada). Andre Denis, president of Oxbow, has hinted that MonoGen might use lower pricing to gain share (see *DTTR*, April 2005, p. 5).

But for now, MonoGen's biggest problem may be its apparent lack of cash. In March, Oxbow revealed that MonoGen has received a demand for repayment of a $4.3 million loan provided by Cardinal Health, which has exclusive marketing and distribution rights in the United States for the MonoPrep products. Oxbow has stated in its previous disclosure documents that this loan was in default and subject to demand for repayment by Cardinal Health.

DTTR speculates that the money problems could result in a sale of MonoGen to one of the larger IVD companies that have the deep pockets that will be needed to go head-to-head against Cytyc and TriPath. Mr. Denis was not available for comment at press time.

Company References

Affymetrix 408-731-5000

Bayer Diagnostics 914-631-8000

Correlogic 301-214-4030

Digene 301-944-7000

Egenix 845-677-5317

Exact Sciences 508-683-1200

GeneFluidics 323-269-0900

Genomic Health 650-556-9300

Johnson & Johnson 732-524-0400

LabCorp 336-229-1127

LabNow 512-329-9998

MonoGen 847-573-6700

OraSure 610-882-1820

Third Wave 888-898-2357

Trinity Biotech 353-1-276-9800

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