Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

The Outlook For China's IVD Market: Market Potential Versus Trade Barriers

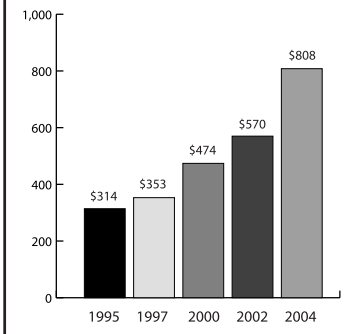
Despite significant barriers to trade, the market for instrument and reagents sales in China is booming and foreign manufacturers are making inroads. Between 2002 and 2004, the Chinese IVD market grew by more than 30% per year to reach $808 million, according to the market research firm McEvoy & Farmer (San Francisco, CA). In fact, there has not been a year in the last decade in which the IVD market in China has failed to grow faster than any other major IVD market, says market researcher Carl McEvoy.

And the growth rate and opportunities for foreign firms will expand as China's overly burdensome regulation of medical devices moves more in line with international practices, he notes.

While tariffs went down when China joined the WTO in 2001, they have yet to simplify or reduce the cost of product registration, which is another of their WTO commitments, says McEvoy. "We have spoken with officials at the State Food and Drug Administration (SFDA) and have been told that this will happen, but they don't expect any change for at least a year," he adds.

For more of our exclusive interview with the principals at McEvoy & Farmer, see *Inside the Diagnostics Industry*, pp. 5-7.

The Chinese IVD Market *($ MM)*



Source: McEvoy & Farmer

Bayer Might Sell Diagnostics Business; But Who Would Buyer Be?

Bayer Group (Leverkusen, Germany) may consider selling its diagnostics business if it succeeds in buying the over-the-counter drug unit of Boots Group Plc. (Nottingham, England), the *Financial Times Deutschland* reported on September 18. The Bayer press departments in Germany and Tarrytown, New York, did not respond to *DTTR* requests for comment. However, the German newspaper says that Werner Wenning, chief executive at Bayer, discussed the possible sale of the diagnostics unit at a recent board meeting. But *DTTR* wonders, who would buy it?

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Bayer Might Sell Diagnostics Business, *from page 1*

The acquisition of Bayer Diagnostics would seem to add to much redundancy and market overlap for a purchase by one of the three largest IVD companies—Roche, Abbott, and Johnson & Johnson (Ortho-Clinical and Lifescan).

The next two largest—Beckman Coulter and Dade Behring—might show greater interest since neither has a self-monitoring blood glucose (SMBG) testing business. In addition, Beckman's new chief executive, Scott Garrett, has a history of engineering big deals (e.g., he was the architect behind the mergers of the diagnostic business at Baxter, DuPont, and Hoechst AG). And earlier this year, Dade chief executive Jim Reid-Anderson stated: "Over the next two to three years there will be consolidation in the industry, and we're well positioned to participate." (see *DTTR*, March 2005, page 7).

An alternative would be for Bayer to spin its diagnostics business out as a separate publicly traded company.

Meanwhile, Bayer seems intent on expanding its over-the-counter drugs unit. Last year, Bayer bought Roche's OTC business for about $2.8 billion. The acquisition nearly doubled annual sales at Bayer's OTC unit to about $3 billion, making it one of the top three nonprescription businesses worldwide.

Boots's OTC business markets a range of well-known brands including Clearasil skin products, Nurofen painkillers, and Strepsils throat lozenges. If successful in its bid for the unit, Bayer's nonprescription business would grow to nearly $4 billion per year of revenue.

The sale of its diagnostics business could help Bayer cover the more than $2 billion it would spend to acquire the Boots's OTC business. In the six months ended June 30, 2005, Bayer Diagnostics generated EBITDA (earnings before interest, taxes, depreciation, and amortization) of 191 million euros (US $228 million) on revenue of one billion euros (US $1.2 billion).

DTTR believes Bayer's diagnostic unit, including SMBG and diagnostics, would fetch around $2.5 billion to $3 billion if sold together, or roughly the amount Bayer would spend to acquire the Boots's OTC business.

Bayer Diagnostics at a Glance *(EUR million)*

	First-Half 2005	First-Half 2004	Change %
Revenue	1,022	954	7.1
Self-monitoring blood glucose	337	309	9.1
Diagnostics	685	645	6.2
EBITDA*	191	173	10.4
Operating result (EBIT)	109	88	23.9

* EBITDA = earnings before interest, taxes, depreciation, and amortization

Source: Bayer

InterGenetics Prepares Launch Of $647 Breast Cancer Test

Dr. Shimasaki

InterGenetics Inc. (Oklahoma City) has completed construction of a new 11,000 square-foot laboratory and headquarters, anticipates getting a CLIA waiver this month (October), and plans to begin marketing its OncoVue breast cancer genotyping test by year's end, Craig Shimasaki, Ph.D., InterGenetic's president and chief executive, tells *DTTR*.

Shimasaki says OncoVue will be priced at $647 per test and projects that 15,000 tests will be performed in the new lab in the first 12 months of operation. If achieved, this would equate to nearly $10 million of revenue ($647 x 15,000 = $9.7 million). An independent validation of the test is currently being conducted at M.D. Andersen Cancer Center (Houston, TX).

The OncoVue test is performed by using regular mouthwash that a woman rinses and then spits into a tube. The mouthwash sample is sent to InterGenetics, where the DNA is extracted and analyzed. Between forty and sixty common gene variants associated with breast cancer are examined as well as the patient's medical history.

Shimasaki says OncoVue is different from other breast cancer genetic tests on the market today because it looks at combinations of genes responsible for things such as DNA repair, cell cycle control, hormone metabolism, and carcinogen metabolism. In general, he says women with certain combinations of gene variations are associated with higher risk for breast cancer.

For example, a woman with a particular polymorphism in the CYP1B1 gene has a 1.3 times greater risk of developing breast cancer than the average woman, while a particular polymorphism in the PHP gene indicates a 1.1 times increased risk, and a polymorphism in the HER2 gene indicates a 0.9 times risk. However, if a woman has a specific genotype with all three of these variants, she is at 3.9 times the average risk of developing breast cancer, according to Shimasaki.

He says turnaround time for the test is 72 hours. Initially, OncoVue will be marketed primarily to a subset of comprehensive breast care centers, but will eventually be available in all breast care and imaging centers that have an interest in the test. Shimasaki also says he's had discussions with several national reference labs interested in licensing the company's testing technology. He notes that InterGenetics is also developing a test for ovarian cancer risk prediction.

InterGenetics at a Glance

Lab/headquarters:	Oklahoma City
President and CEO:	Craig Shimasaki, Ph.D.
Chief scientific officer:	David Ralph, Ph.D.
Vice president, co-founder:	Eldon Jupe, Ph.D.
Employees:	25
Test/price:	OncoVue/$647
Projected revenue, 2006:	$9.7 million

Source: InterGenetics

InterGenetics is a spin-off of the Oklahoma Medical Research Foundation (OMRF); current owners include OMRF, Presbyterian Health Foundation, Oklahoma Life Sciences Fund, Sam Noble Foundation, Swisher Family Trust, and about 20 individual investors.

Prior to joining InterGenetics in 2002, Shimasaki was vice president of research and chief operating officer at ZymeTx (Oklahoma

City), where he co-invented the first rapid diagnostic test (ZstatFlu) for the detection of influenza types A and B virus from a throat swab specimen.

Two years of mild flu seasons and a downturn in the stock market forced ZymeTx into a bankruptcy reorganization in 2002. When it emerged from bankruptcy a year later, the firm sold its ZstatFlu inventory and licensed the rights to most of its assets.

Shimasaki says that among the lessons learned from his experience at ZymeTx are: 1) be aware of the risks of one product position, especially when that product is seasonal; 2) resist the urge to expand when it requires expenditures that are a major percentage of your capital; and 3) raise more money than you think you'll need.

Amazon Now Selling Gene Testing Kits, But Is Anyone Buying?

Online retailer Amazon.com has begun selling genetic test kits made by Catgee (Somerset, England) for $29.99 (DNA storage only) and $139.90 (storage plus a genetic profile). The kits come with a cheek swab, sample card, and a sample storage container.

The DNA storage option involves receiving a pack in the mail, taking a saliva sample with a swab from inside of your cheek, and applying the swab to the storage card. The consumer then puts the card in an airtight self-sealing pouch; the pouch goes in a tin container. That's all there is to it. The consumer can then store the tin in a bank deposit box or their sock drawer.

Why would anyone want to do this? Because it will tell future generations all there is to know about you, and, as genetic science advances, future generations will have a far greater insight into previous generations from your stored DNA, according to the Catgee Web site.

The genetic profiling option involves sending a specimen back to Catgee, which ships the specimen to a contracted lab for testing. Catgee then ships the unique DNA code and a color image back to the consumer. Why do this? Because "It's fun and exciting to see how your DNA code compares with the codes of unrelated friends and with entire populations," according to Catgee.

Catgee was founded by David Nicholson in 2002 and began selling its DNA kits in England that same year, then expanded sales into the United States during the start of 2003. Catgee gets its name from the four base pairs of DNA, which are cytosine, adenine, thymine, and guanine. Scientists usually describe them by their initials C-A-T-G, hence Catgee.

Nicholson says that the company has sold about 60,000 kits around the world since being formed and that sales have jumped since Amazon began offering them. However, *DTTR* notes that Catgee's DNA Storage and Profile Kit ranks only #44,239 in terms of health and personal care items sold through Amazon. The top three selling products are more practical items: 1) Remington Electric Shaver; 2) Omron Premium Pedometer; and 3) Panasonic Nose & Ear Hair Groomer.

China: The Next Great IVD Market Or Bureaucratic Nightmare?

Carl McEvoy

With a gross domestic product of more than $1.4 trillion, China surpassed Italy last year to become the world's sixth largest economy, according to the International Monetary Fund. And the country's $800+ million IVD market now ranks as the sixth largest (after the United States, Japan, Germany, Italy, and France) and is growing at well more than double the 6% to 7% annual rate of the world market. For insight into the current state of the Chinese IVD market and its outlook, we interviewed Carl McEvoy and Michael Farmer of the eponymous market research firm McEvoy & Farmer. Here's what they had to say:

Describe the Chinese laboratory market today?

McEvoy & Farmer: The lab business in China is highly stratified. Of some 17,000 government-owned hospital labs in China, only 7,000 can be considered automated. These 7,000 run nearly two-thirds of China's lab work.

China has no private commercial lab or private hospital business to speak of because its doctors have not yet been liberated by the government to operate private medical practices. As a result, virtually all end-users of lab instruments and reagents are government hospitals.

Historically, nearly all IVD instrumentation used in China has been imported from the United States, Italy, or Japan. But some domestic companies, most notably Shenzhen-based Mindray, are beginning to make inroads in semi-automated and automated chemistry and hematology analyzers. This is a real trend. We expect more and more instrumentation will be made in China, and pretty soon the multinational IVD firms will be feeling the heat of competition from Chinese instrumentation companies in North America and Europe.

The Chinese IVD Market, 2004

Market Segments	*RMB*	*US Dollars*	*Percentage*
Immunochemistry	1,968,156,000	$237,700,000	29%
Routine chemistry	1,746,252,000	210,900,000	26%
Hematology	822,204,000	99,300,000	12%
Critical care chemistry	423,936,000	51,200,000	6%
Molecular testing	320,436,000	38,700,000	5%
Urine chemistry	311,328,000	37,600,000	5%
Coagulation	231,840,000	28,000,000	3%
Other markets*	869,400,000	105,000,000	14%
Totals	6,693,552,000	$808,400,000	100%

Note: includes instrument and reagent sales; exchange rate: $1 = 8.28 Renminbi (RMB);
*Includes microbiology, diabetes and pregnancy self-testing, cytology, and a few other smaller markets which together add up to roughly 14% of the total market, or about $105 million.
Source: McEvoy & Farmer

As for the reagent market, the Chinese are open-system oriented and the majority of routine reagents used by its labs come from local reagent makers that sell at extremely low prices. The exception is the immunochemistry market where closed systems made by foreign IVD makers have made inroads.

In 2005, we estimate that imports accounted for roughly 55% to 60% of the total China IVD market.

What's the potential for the China market?

Look at it this way—Europe, Japan and North America average $17-22 of per capita annual IVD spending. China is still at 65 cents a year.

Note: The Chinese Ministry of Health estimates that 40% to 60% of the country's farmers, or one-third of China's total population, can't afford medical treatment in hospitals. In some poverty-stricken regions, especially in western China, up to 60% to 80% of the sick die at home as they have no money for the hospital.

The farmers are reluctant to go to hospital mainly because their meager incomes and the medical costs are disproportionate. In 2003, the per capita annual income for rural Chinese averaged only about $316, while the average medical cost for every hospitalization was $269, or almost all of their entire earnings for the year.

Today, what does it take for an IVD company to be successful in China?

Most importantly, IVD firms need to offer products that are profitable to labs. The labs in China may be owned by branches of the government, but they generate their own revenue and are more astute at maximizing their profits than most private labs in other countries.

Profitability depends on the margin between selling price to the lab and the price listed for that test on the provincial reimbursement list. International firms have so far successfully lobbied for higher test reimbursement, so in many cases an imported test can be more profitable for the lab even though the reagent price is higher than the local competition. This pricing gap has become however a target for reformers in the health ministry, so we should not expect it to last forever.

Who are the three largest IVD distributors in China?

Fosun, a local manufacturer from Shanghai, sells the Long March brand of chemistry reagents along with many other products, but it is their strong position in chemistry that has led them to develop a broad distribution network that reaches all levels of hospitals.

Hong Kong's Vastec Medical Ltd. distributes around 15 international lines of IVD products and has as wide a sales and distribution network as we have seen in China.

Sysmex started working in China in the 1970s and reaches laboratories of all levels since they sell both high- and low-end hematology systems. While they are a multinational company, they are now also becoming a distributor for other lines. These currently include Transasia and Medica. We expect to see other lines added to their network as well.

What percentage of final selling price do Chinese distributors typically earn today?

The term distributor can be used to describe a company like Vastec that imports, warehouses, sells, and services the product, or it can be used for the person with *guanxi* (connections) that simply arranges the final delivery and payment. In the first example, the distributor will earn as much as 50% of the sale price, while in the second the average is closer to 20%.

Who are the top IVD companies doing business in China (by revenue from IVD sales to China)?

The top two local companies are Fosun, mentioned above, and Kehua, a reagent company that is strong in immunochemistry and routine chemistry. The top two international companies would be Beckman-Coulter and Sysmex.

But all of the major IVD vendors are taking the China market very seriously. The margins in China are generally lower, but the growth is great.

What is the outlook for privatizing the practice of medicine in China?

We've been covering the Chinese market now for more than 10 years, and privatization has always been on the horizon. There are a very small number of private labs and small hospitals that serve wealthy Chinese and ex-patriots, but the outlook for widespread privatization is unclear.

China's new Minister of Health, Gao Qiang, recently gave a speech where he said hospitals motivated by profit, instead of caring for the sick, were to blame for some of the problems plaguing the country's health system. He said the next step of medical reform will focus more on public interest and affordability. So we don't expect any dramatic movement toward privatization in the near term.

However, despite the lack of officially sanctioned private practice, there is a black market. Chinese doctors sometimes practice medicine at their houses to self-paying patients after their government hospital shifts are over.

Barriers to Trade in China

China maintains significant barriers to trade, despite joining the World Trade Organization (WTO) and agreeing to WTO obligations, according to industry trade group AdvaMed (Washington, DC). In a December 2004 letter to the U.S. Department of Commerce, AdvaMed outlined the following trade barriers to imported medical technology:

- Duplicative type testing of individual device samples by both the State Food and Drug Administration (SFDA) and the Administration of Quality Supervision & Quarantine (AQSIQ) is often required for a wide range of products. Moreover, many provincial authorities add additional testing or certificate requirements on top of testing by the SFDA and AQSIQ.
- SFDA has yet to move toward a quality systems approach focusing on design and manufacturing systems, processes, and procedures for ensuring quality products—an approach the rest of the world is moving toward.
- There are excessive delays and backlogs by China's regulatory agencies. Manufacturers are required to renew product licenses every four years. However, a license could expire while waiting to be renewed due to excessive and repetitive requirements. In addition, license renewals are not limited to the submission of new information pertaining to the product, but require resubmission of previously submitted information.
- China maintains import prohibitions on foreign blood and plasma products. Despite the availability of state-of-the-art technology from foreign manufacturers, China relies exclusively on local blood screening systems.

Source: AdvaMed

National Reference Labs Going Directly To Universities For New Tests

The national reference labs now seem to be digging deeper into the pipeline of promising esoteric testing technologies. At least two (Genzyme Genetics and Quest Diagnostics) of the six major national reference labs are now starting to secure exclusive licensing deals directly with universities and academic medical centers thereby cutting out the middleman role played by the big diagnostic test manufacturers and smaller startups.

Genzyme Genetics' deal with UCLA Jonsson Cancer Center is the most recent example of the way reference labs are going straight to researchers for new esoteric tests. Under this agreement, Genzyme has secured exclusive worldwide diagnostic rights to secondary BCR-ABL gene mutations that are associated with drug resistance to Gleevec, the current first-line therapy for patients with chronic myeloid leukemia (CML). Additional terms of the agreement were not made public.

The discovery of the BCR-ABL mutations was made by researchers at UCLA in 2001.

The BCR-ABL gene mutation is the specific target for Gleevec and is found in 95% of patients with CML. Secondary mutations in the ABL portion of the gene correlate with treatment failure or relapse in most patients on Gleevec therapy.

Through this license, Genzyme will be the first laboratory to develop and market a diagnostic test to detect a significant portion of these secondary BCR-ABL mutations and monitor resistance in CML patients being treated with Gleevec. Genzyme says it will have a homebrew version of the test on the market by year's end.

The American Cancer Society estimates that there will be approximately 4,600 new cases of CML diagnosed in 2005. Approximately 25,000 CML patients are living in remission on therapy in the United States today.

Genzyme's announcement of its exclusive licensing deal with UCLA Jonsson Cancer Center comes on the heels of a similar deal struck earlier this year with Massachusetts General Hospital (MGH) and Dana-Farber Cancer Institute (DFCI), which gave Genzyme exclusive, worldwide diagnostic rights to their discovery of the epidermal growth factor receptor (EGFR) gene mutations.

The licensing deal with MGH and DFCI was signed in May. In September, Genzyme announced it had developed a test for the EGFR markers that can be used to help identify patients who are most likely to respond to targeted therapies (e.g., Tarceva and Iressa) for the treatment of non-small cell lung cancer (NSCLC). Genzyme's test, which is priced at $975, examines tumors removed by biopsy for mutations that make them susceptible to treatment.

Quest's Exclusive Deal With M.D. Anderson

Genzyme is not the only reference lab bypassing the traditional middlemen and going directly to the source for exclusive access to new esoteric tests. Earlier this year, Quest Diagnostics announced a licensing agreement with the University of Texas M.D. Anderson Cancer Center that gave it exclusive access to a new blood testing technology for diagnosing and monitoring leukemia and lymphoma (see *DTTR*, March 2005, page 3).

UBS Conference Highlights: Abaxis, OraSure, Meridian, Biosite

At the UBS Global Life Sciences Conference, Sept. 26 to 29 in New York City, the chief executives of several publicly traded point-of-care test makers gave presentations to mutual fund managers and hedge funds. Here are some highlights:

Clint Severson, chairman and chief executive of **Abaxis** (Union City, CA), said, "No one has ever successfully sold a product [the Piccolo point-of-care analyzer] like ours before. We have to figure it out ourselves." Severson noted that Abaxis was on its third sales manager for the Piccolo and was still experimenting on pricing and distribution. "Once we figure these things out, we'll scale up," he said.

The Piccolo is a portable blood analyzer (15 pounds) that provides test results in 13 minutes from 100 microliters of whole blood. The menu currently stands at 23 tests, including CLIA-waived tests for a lipid panel and ALT (alanine aminotransferase), AST (aspartate aminotransferase), and glucose.

Severson said Piccolo's menu now covers 96% of the clinical chemistry volume run through the typical centralized laboratory. Abaxis is now targeting the immunoassay market and has tests for C-reactive protein and creatine kinase MB under development, according to Severson.

In the fiscal year ended March 31, 2005, Abaxis sold 293 Piccolo analyzers, down from 363 in fiscal 2004. However, sales of disposable reagent discs grew 85% to 404,000 discs (average price of $4.51 per disc) from 218,000 discs ($4.80 per disc). "This shows that when we sell a Piccolo, it gets used," noted Severson. He said the Piccolo's key markets include urgent care centers, small hospitals, oncology clinics, CLIA-licensed physician practices, and the military.

Douglas Michels, president and chief executive of **OraSure Technologies** (Bethlehem, PA), said the company has begun discussions with the FDA regarding bringing its OraQuick Rapid HIV-1 & 2 antibody test to the over-the-counter market. The test is already FDA approved and CLIA waived for testing on saliva, whole blood, or plasma. As of the three months ended June 30, 2005, OraQuick was generating annualized revenue of $20 million, according to Michels.

He estimates that the total clinical market in the United States for rapid HIV tests is 17 million tests per year, including 10 million at hospitals, three million each at public health clinics and physician offices, and one million from the Centers for Disease Control and Prevention. Michels noted that a distribution deal with Abbott was resulting in significant uptake of OraQuick use in hospitals.

In August, OraSure obtained a license from Ortho-Clinical Diagnostics and Chiron Corp. to patents relating to the hepatitis C virus. Michels said the company has already developed a prototype rapid test for HCV that will work on saliva or blood samples. He noted that there are 170 million people worldwide with hepatitis C, which is four to five times as many as the HIV population.

In addition, Michels said the company's oral fluid test (aka Intercept) for drugs of

abuse was growing 50% per year. And he expects a boost once SAMSHA publishes new guidelines for alternative test methods like oral fluid and hair testing.

Finally, Michels said that OraSure is looking for additional products or companies to acquire in the infectious disease testing market.

Jack Kraeutler, president and chief operating officer at **Meridian Biosciences** (Cincinnati, OH), said the company will continue bringing three to five new products to market each year. Most recently, Meridian launched its Immunocard C. difficile Toxins A & B rapid test in the United States. The company now has five C. difficile tests on the market that generate a combined $20 million per year of revenue. Kraeutler said Meridian plans to launch a new test for neurovirus, which causes diarrhea and is common on cruise ships, early next year.

Chris Twomey, chief financial officer at **Biosite** (San Diego, CA), said the company's Triage BNP rapid test was now being used by 3,000 hospitals and 500 physician offices. He pegged the current worldwide BNP market at $300 million, of which Biosite has nearly a 50% share.

Biosite says the worldwide market for BNP testing could expand to $800 million per year.

The FDA recently cleared a new indication for the Triage BNP Test. It can now be used to help physicians assess the risk of mortality or rehospitalization in heart failure patients. Previously, the test was cleared as an aid in the diagnosis of heart failure, assessment of disease severity, and in the risk stratification of patients with acute coronary syndromes.

Twomey said the test can now be used as a pre-discharge/prognostic indicator for patients hospitalized for heart failure. The potential market is 40 million tests per year, or $800 million, assuming $20 per test sale, according to Twomey.

He said Bayer and Abbott were Biosite's two main competitors in the BNP market. "The NT pro-BNP tests sold by Roche and Dade have not been all that successful to date," Twomey added.

Ron Zwanziger, chief executive at **Inverness Medical Innovations** (Waltham, MA), said the company's consumer diagnostics business (OTC pregnancy and ovulation tests/revenue of $164 million per year) is highly profitable and allows for significant investment in rapid cardiac tests. The company's total R&D budget for 2005 is $45 million, including $35 million for rapid cardiac tests, according to Zwanziger.

Inverness wants to bring rapid cardiac testing into the OTC market.

Later this year, Zwanziger says Inverness will launch an ischemia modified albumin (IMA) test for use on Roche's automated analyzers. The IMA test will be used to help rule out heart attacks and will ultimately be developed into a rapid test, he said. Through a license with Roche, Inverness is also developing a NT pro-BNP test that will be combined with another marker (urotensin) for improved accuracy in diagnosing heart failure.

"We're looking to bring rapid cardiac testing away from the emergency department to the physician office and ultimately into patient's homes," said Zwanziger. "This will allow for preventive testing, rather than post-event testing," he added.

IVD Stocks Up 6% Year To Date Led By Rapid Test Makers

Twenty-five IVD company have risen an unweighted average of 6% year to date through October 7, 2005, with 11 stocks up in price, one unchanged, and eight down. This compares with no change for either the S&P 500 Index or Nasdaq indices.

Interestingly, the three best-performing IVD stocks were all relatively low-tech rapid test makers, while the two worst performers were in the high-tech molecular diagnostics area.

Quidel (San Diego, CA), which makes rapid influenza, strep, and pregnancy tests, has more than doubled so far this year to $10.48 per share for a market capitalization of $345 million. **Meridian Biosciences** (Cincinnati, OH), which makes rapid infectious disease tests, is up 81% to $21.21 per share for a market cap of $526 million. **OraSure** (Bethlehem, PA), which makes the OraQuick rapid HIV and drugs-of-abuse tests, is up 37% to $9.16 per share for a market cap of $420 million.

The two worst performing stocks have been **Exact Sciences** (Marlborough, MA), down 48% to $2 per share for a market cap of $52 million, and **Third Wave Technologies** (Madison, WI), down 44% to $4.85 per share for a market cap of $196 million.

IVD Stock Performance, YTD Through October 7, 2005

Company (ticker)	12/31/04 Price	10/7/05 Price	YTD % Chg	P/E Ratio	Div. Yield
Quidel (QDEL)	$5.08	$10.48	106%	N/A	N/A
Meridian (VIVO)*	11.70	21.21	81	43	1.5%
OraSure (OSUR)	6.72	9.19	37	N/A	N/A
Dade Behring (DADE)*	28.00	35.39	26	39	N/A
Affymetrix (AFFX)	36.55	45.02	23	44	N/A
Cholestech (CTEC)	8.20	9.74	19	23	N/A
Ventana (VMSI)	32.00	35.94	12	54	N/A
Luminex (LMNX)	8.88	9.83	11	N/A	N/A
Immucor (BLUD)	23.51	25.95	10	50	N/A
Bayer (BAY)	33.98	36.48	7	33	1.5%
Digene (DIGE)	26.15	27.77	6	N/A	N/A
Biosite (BSTE)	61.54	61.34	0	22	N/A
Inverness Medical (IMA)	25.10	24.46	-3	N/A	N/A
Johnson & Johnson (JNJ)	63.42	61.34	-3	20	2.1%
Abaxis (ABAX)	14.49	13.80	-5	69	N/A
Bio-Rad Labs (BIO)	57.37	54.32	-5	19	N/A
Gen-Probe (GPRO)	45.21	42.65	-6	45	N/A
Cytyc (CYTC)	27.57	25.74	-7	31	N/A
Abbott Labs (ABT)	46.65	42.70	-8	19	2.5%
Becton Dickinson (BDX)	56.80	51.83	-9	21	1.3%
Diagnostic Products (DP)	55.05	49.41	-10	23	0.5%
TriPath Imaging (TPTH)	8.97	7.61	-15	76	N/A
Beckman Coulter (BEC)	66.99	51.21	-24	16	1.0%
Third Wave (TWTI)	8.60	4.85	-44	N/A	N/A
Exact Sciences (EXAS)	3.83	2.00	-48	N/A	N/A
Unweighted Avg.			6%		

*stock prices for Meridian and Dade Behring have been adjusted for stock splits

Source: *DTTR*

G-2 Insider

Could Cervical Cancer Vaccine Replace Need For Pap Tests?

News of an experimental vaccine that prevents most cervical cancers was greeted with "so what" by investors in three Pap testing companies whose businesses could be upended by a vaccine. On October 6, Merck announced that the first major study on its experimental vaccine (Gardasil) to prevent cervical cancer found it was 100% effective at blocking the disease and lesions likely to turn cancerous.

The genetically engineered vaccine was shown to block infection with two of the 100-plus types of human papilloma virus, HPV 16 and 18. The two sexually transmitted viruses together cause about 70% of cervical cancers. If approved by the FDA, Gardasil could reach the market as soon as 2006.

Merck shares rose 6% on the day of the announcement. As for the cervical cancer test kit makers: Cytyc's shares were down 4%; Digene was up 3%; and TriPath Imaging was up 2%. Go figure.

Company References

Abaxis 510-675-6500

Bayer Diagnostics 914-631-8000

Biosite 858-455-4808

Catgee 800-828-1545

Genzyme Genetics 800-357-5744

InterGenetics 405-271-1720

McEvoy & Farmer 206-282-2570

Meridian Biosciences 513-271-3700

OraSure 610-882-1820

Quest Diagnostics 201-393-5000

Third Wave 888-898-2357

In response to *DTTR*'s article last month that questioned whether Third Wave's recently cleared Invader UGT1A1 test would be made widely available (see *DTTR*, October 2005, page 1), the company gave the following response:

"Third Wave is committed to ensuring that our recently cleared Invader UGT1A1 test is available for any doctor to order in the treatment of his or her patients. To that end, our UGT1A1 product is already being used by several thought-leading laboratories across the country, including Dartmouth-Hitchcock Medical Center and other laboratories. We look forward to making an announcement soon about our plans to distribute the test more broadly."

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