



Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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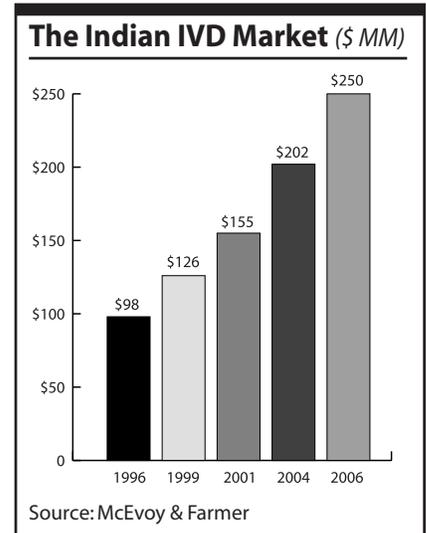


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No Growing Pains For India's Booming IVD Market

Despite the occasional logistical complexities of transporting in vitro diagnostic equipment across Indian state lines, which are often fortified with trade barriers, the market for instrument and reagent sales in India is booming, and foreign manufacturers are making inroads. India now boasts 26,000 active clinical laboratories, and that number continues to climb, spurred by minimal regulation of the laboratory market and reasonable financing. Demographic trends in India are further invigorating the IVD marketplace, as an increasingly prosperous and urban-dwelling population seeks enhanced healthcare services.

Between 2001 and 2006, the Indian IVD market grew from \$155 million to \$250 million, according to the market research firm McEvoy & Farmer (San Francisco, CA), which specializes in research on emerging IVD markets. According to the firm's most recent study, its fifth in the last decade, India's IVD market is growing between 15% and 20% annually. "We have never been more optimistic," Carl McEvoy tells DTTR. For our exclusive interview with Carl McEvoy, see *Inside the Diagnostics Industry*, pp. 5-8. 🏠



Siemens To Buy Bayer Diagnostics For \$5.31 Billion

Only months after announcing that it would enter the IVD market with the purchase of Diagnostic Products Corporation (Los Angeles, CA), German industrial giant Siemens (Erlangen, Germany) has signed an agreement to acquire the Diagnostics Division of Bayer (Leverkusen, Germany) for €4.2 billion (\$5.31 billion), nearly three times its annual (2005) sales of €1.4 billion. The transaction, from which Bayer expects net proceeds of €3.6 billion, should close in the first half of next year.

The acquisition of Bayer Diagnostics, intended to make Siemens' medical technology business competitive with those of such conglomerates as General Electric and Philips, will significantly deepen and broaden

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▲ Siemens To Buy Bayer Diagnostics, from page 1

the diagnostic capabilities of the company, particularly in molecular diagnostics. In addition to genetic analysis, the Bayer division will give Siemens an impressive portfolio in clinical chemistry, laboratory automation, and hematology.

“The acquisition of Bayer Diagnostics is part of our targeted strategy to create the healthcare industry’s first integrated diagnostics company by combining the entire imaging diagnostics, laboratory diagnostics, and clinical IT value chain under one roof,” said Klaus Kleinfeld, M.D., president and CEO of Siemens.

Last fall, *DTTR* speculated that Bayer was looking to unload its diagnostics business (see *DTTR*, November 2005, pp. 1-2), perhaps to free up money to invest in purchasing the over-the-counter drug unit of Boots Group (Nottingham, England). However, shortly thereafter, Bayer Diagnostics president Tony Bihl assured *DTTR* that after a recent strategic assessment, the company had confirmed that the diagnostics division would continue to play a key role in the company’s healthcare group. According to Bihl, the mandate for Bayer’s centralized diagnostics business was profitable growth, which was defined as pretax margins of 10% to 12%.

“The decision to divest our Diagnostics Division is fully in line with our strategy for systematically aligning our healthcare business,” said Bayer Management Board Chairman Werner Wenning. “We are concentrating on pharmaceuticals for both humans and animals, and products that can be promoted directly to patients.”

The company has wasted no time in pursuing this strategy with its recent takeover of Schering (Berlin, Germany), a move that it completed in June by gaining control of over 90% of stock in the company. The purchase, which was the biggest transaction in Bayer’s history, will “create a powerful, world-class pharmaceutical company based in Berlin,” according to Hubertus Erlen, M.D., chairman of the Schering executive board.

In July, Bayer announced that its Diabetes Care division, one of the world’s largest self-test diagnostic businesses, acquired privately held Metrika (Sunnyvale, CA), the company that manufactures and markets A1CNow, a glucose testing device for diabetics. The portable system enables clinicians and patients to monitor glycated hemoglobin (HbA1c), which is an index of a patient’s blood sugar control over the previous two to three months. 🏠

Chicago Forensics Lab Develops Genetic Test For HIV Resistance

Independent Forensics (IF; Chicago, IL) has developed a test to determine an individual’s genetic predisposition to HIV-1 disease progression. Results of the test, which analyzes the chemokine (C-C Motif) Receptor 5 (CCR5) on t-cells, can also help clinicians determine the most effective use of treatment methods, such as CCR5 antagonists, for HIV-infected patients.

“The development of the CCR5 haplotype test really puts us on the shoulders of giants,” says Karl Reich, IF’s chief scientific officer. “Years of studies have proven the importance of CCR5 receptors in determining HIV progression levels.”

CCR5 is the primary co-receptor for HIV-1. It plays an important role in autoimmune and inflammatory disorders by affecting the trafficking of effector T cells and monocytes to diseased tissues. CCR5 has natural genetic variations that alter levels of receptor expression, and certain haplotypes have been shown to influence the rate at which HIV progresses to AIDS.

Insight into a patient's CCR5 haplotype can help clinicians determine the best use of CCR5 antagonists. These in-development drugs, such as Pfizer's maraviroc, are viewed by many as the next big class of antiretroviral compounds. They seek to inhibit the docking of HIV to the CCR5 receptor site.

IF's CCR5 test uses buccal swab collection that can be performed at the patient's home. Following DNA extraction and CCR5-specific amplification, the DNA is analyzed with a Beckman Coulter CEQ8000 Genetic Analyzer to detect single nucleotide polymorphisms (CCR5 alleles) and deletions ($\Delta 32$). Seven variations in the *cis*-regulatory region and one change in the coding region are examined. Disease progression rates of the patient can then be categorized into epidemiological classes (fast, neutral, or slow progressor) based on their CCR5 haplotype pairs. Results are available in three weeks.

Founded by Jack Keehma, its current chief operating officer, IF offers a range of forensic services, including paternity testing and Rapid-Stain Identification tests for saliva and semen. The company is now focused on expanding its molecular test offerings. In the pipeline are DNA-based tests for drug metabolism pathways and DNA-based tests for susceptibility to depression. 🏠

Genoptix Will Offer Veridex's CellSearch Breast Cancer Test

Genoptix (Carlsbad, CA) will be the second lab in the United States to offer CellSearch Circulating Tumor Cell (CTC) test, which is manufactured by Johnson & Johnson-owned Veridex (Warren, NJ). The test is used to predict progression-free survival and overall survival in patients treated for metastatic breast cancer. Quest Diagnostics (Lyndhurst, NJ) has offered the test since 2004.

CellSearch CTC is the only FDA-cleared assay that identifies circulating tumor cells in breast cancer patients. Using Veridex's CellSearch platform, the kit-based test characterizes and counts epithelial circulating tumor cells shed into the blood. Cells are labeled with an epithelial adhesion molecule and further distinguished from common leukocytes by the addition of CD45 labeling and tagging with cytokeratins specific to epithelial cells. A CTC count of five or more per 7.5 milliliters of blood is predictive of shorter progression-free survival and overall survival. CTC levels can also help in the management of metastatic breast cancer patients and monitoring of therapy efficacy.

"The CellSearch CTC test complements our current offering by helping to determine efficacy of therapy and disease progression in metastatic breast cancer," Genoptix Vice President Susan Bailey tells *DTTR*. "Genoptix will bill third-party payors for the test, most of whom are already reimbursing for CPT codes associated with the technology." Physicians will get results of the test back in two to three days.

Veridex, which specializes in oncology diagnostics, continues to develop its two complementary product lines. In addition to the CellSearch line, its GeneSearch products are based on molecular technology for gene expression profiling of a range of cancers. CLIA- and CAP-certified Genoptix combines proprietary and exclusive tests in order to provide “personalized medicine services” primarily related to the treatment of blood and bone marrow malignancies. 🏠

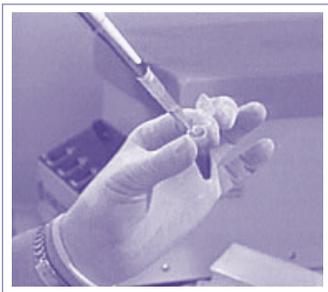
Communication Is Key For Physician ‘Buy-In’ To Molecular Testing

As molecular-based laboratory tests replace traditional laboratory techniques, the technological and methodological shift is creating a dilemma for both clinicians and laboratories. One critical concern is how to help clinicians stay abreast of the available diagnostic offerings and ultimately to earn their “buy-in” for assays that can provide more detailed and informative results, often in a fraction of the time of older, non-molecular methods.

In general, clinicians are accepting molecular-based tests with little resistance. According to Lynel Vallier, administrative director of the Boulder Community Hospital Reference Laboratory (Boulder, CO), “The majority of physicians are accepting of molecular testing. They understand that it’s new technology. They understand the sensitivity and specificity of the assays.” The minority, he notes, don’t care. “They just want to order a procedure, and they want a result back.”



In some cases, outside forces have pushed molecular diagnostics to the forefront of physicians’ attention. In the mid-1990s, HIV viral load testing was approved by the FDA. Almost simultaneously, several new HIV drugs were approved and came on the market. This increased awareness of molecular testing for infectious diseases. Whether it was for molecular testing per se or for the fast, reliable, and sensitive testing that went hand-in-hand with new treatments for HIV patients could be debated. It was during this period that molecular-based infectious diseases tests began to increase.



Another example of outside forces pushing, perhaps inadvertently, molecular-based testing was in 2001, when the American College of Obstetricians and Gynecologists (ACOG) modified their guidelines regarding cystic fibrosis testing (CF) and recommended that all Caucasian couples considering pregnancy should be tested. This created a dramatic increase in demand for CF testing. This is something of a chicken/egg scenario. The CF tests were molecular-based. No comparable test method was available. Had there been and ACOG had made the same recommendation, test demand would have increased, molecular-based or not.

Vallier notes that manufacturers of molecular diagnostic assays are targeting physicians in their advertising and marketing campaigns as well as the laboratories themselves. “There’s direct marketing to the physicians from the manufacturers. If you have good and heavy marketing, the physicians will come on board.” 🏠

inside the diagnostics industry

India's IVD Market Comes Of Age On World Stage



Carl McEvoy

With a gross domestic product of \$3.63 trillion, India is the world's fourth-largest economy as measured by purchasing power parity (PPP), according to the International Monetary Fund. When measured in USD exchange-rate terms, it is the world's twelfth largest economy, with a 2005 GDP of \$775 billion. The country's ~\$250 million IVD market is growing at more than double the 6% to 7% annual rate of the world market. For insight into the current state of the Indian IVD market and its outlook, we interviewed Carl McEvoy of the market research firm McEvoy & Farmer. Here's what he had to say:

Describe the Indian laboratory market today.

McEvoy: India has more than 26,000 active clinical laboratories, and the number continues to expand. This is true not only at the automated level, but at all levels, as new laboratories of all sizes continue to open. The number of automated chemistry laboratories in India has grown from approximately 700 in 2004 to the current level of 1,100.

The laboratory market is largely unregulated, with accreditation being voluntary through the government's National Accreditation Board for Laboratories (NABL). This is under the Department of Science and Technology. This, plus growth in the market and reasonable financing, has contributed to the proliferation of private laboratories in India.

The Indian IVD Market, 2006					
Sectors		Crores	Rupees	US Dollars	
Routine Chemistry		468	4,683,135,500	\$105,239,000	42%
Immunochemistry		348	3,478,149,637	\$78,160,666	31%
Hematology		163	1,634,485,000	\$36,730,000	15%
Critical Care Chemistry		50	497,287,500	\$11,175,000	5%
Urinalysis		38	375,023,750	\$8,427,500	3%
Coagulation		25	254,718,000	\$5,724,000	2%
Molecular Testing		12	124,600,000	\$2,800,000	1%
Exchange Rate	44.50				
Total Market		1,105	11,047,399,387	\$248,256,166	100%
<p>Note: Includes instrument and reagent sales; the total market is calculated both in US dollars and in rupees (Rs) and <i>crore rupees</i> (RsCr), which is the vernacular of Indian commerce. The <i>crore</i> is a uniquely Indian unit of measurement, equal to 10 million. At the current exchange rates, RsCr 1 is roughly US\$225,000.</p> <p>Source: McEvoy & Farmer</p>					

"The market is growing between 15% and 20% per year, and we see no reason why this rate of growth should not continue for the next decade," says McEvoy.

The IVD market in India is roughly one-fourth public and three-fourths private. We include the corporate hospitals from the steel, railway, coal, and other industries in the private sector.

The characteristics of the public and private sector markets are quite different. The public sector buys more basic products and purchases more instruments in relation to reagents than the private sector. This is because instruments have separate budgets, and there is a lack of coordination between these that results in laboratories often having instruments but running out of reagents. Private sector buyers, on the other hand, seek out a rational balance of instrument versus reagent purchases and now are often acquiring instruments by reagent rental.

What changes have you seen in the last two years in India's IVD market?

McEvoy: In addition to the general market growth of the last two years, two important trends have occurred in this time.

First, the last remaining major international manufacturers have finally set up their own offices. Over the last two years, Roche has bought back the full rights to distribute their products from Nicholas Piramal, Beckman Coulter has terminated their long-term relationship with Wipro and have just established their own office, and Dade Behring has become independent of Ranbaxy, which simultaneously spun off their diagnostic distribution arm which is now called Diagonova. ABX has also set up an office recently, though the bulk of their distribution efforts remain with bioMérieux. Finally, Audit has acquired Urilab Systems-Diagnostics as their local office in India. At this point, no major international manufacturer lacks its own office in the country.

The second trend is the arrival of products from China. Two years ago, we found only Mindray, Acon, and Duri in India. Today we find that Mindray is much more active and is promoting automated instrumentation through multiple distributors. Acon and Duri continue to be distributed, and a host of small Chinese instrument companies, including Rayto, Perlong, Maysun, Uritest, and Beijing Shinning Sun, are in the market.

While international manufacturers setting up their own offices is a trend that has just about run its course, the arrival of Chinese products is a trend that is only beginning. We know of over 100 IVD manufacturers in China, and all of them are eager to become exporters. They are clearly the price leaders and have already exerted a downward pressure on instrument and rapid strip prices in India. We expect to see this continue, and we expect to see China work its way up the technology ladder to more and more complex products.

What does it take for an IVD company to be successful in India today?

McEvoy: Well, the good news is that we don't know of any diagnostic company that is not currently successful in India. This rising tide has lifted all boats, so it is just an issue of whose boat is doing best!

But aside from the basics of a good product at a good price, distribution and service are the keys to success in India. Logistics are not easy in this country where states erect barriers to trade as if they were small countries. Moving instruments and reagents around the country is a challenge, and companies that can do this well are rewarded by the market. We have also seen that the most successful companies put a great emphasis on rapid response to service needs. Having a reputation of providing good service over many years is a great asset.

Who are the top domestic IVD companies in India?

McEvoy: Transasia, the long-term Sysmex partner, is the leading domestic company. In addition to their new joint-venture relationship with Sysmex, Transasia is a manufacturer of automated chemistry instruments and distributes nine other lines of IVD products.

The Tulip Group is a major producer and exporter of rapid tests and works closely with Lilac, a distributor with a large portion of the immunochemistry market.

Spotlight on India's Top IVD Companies

Transasia Biomedicals

India's leading diagnostic instrumentation company was founded in 1979 by 29-year-old electrical engineer Suresh Vazirani as a marketing firm for imported diagnostic instruments and began manufacturing its own products (instruments and reagents) in 1993. Its joint ventures include relationships with Sysmex, Nittec, Biohit, and Trace. The company now exports its products to 30 countries, including the United States, Germany, China, Korea, Australia, and Taiwan. ISO-9002 certified Transasia has over 3,500 installations to its credit and a sales force that operates from 27 locations throughout India,

The Tulip Group

Headquartered in the Indian state of Goa, the Tulip Group consists of eight independent diagnostic companies that came together in 1988 to form a leading manufacturer and marketer of in vitro diagnostic reagents and kits. The companies are:

- Tulip Diagnostics:** Assay systems and microbiology
- Orchid Biomedical Systems:** Membrane-based immunodiagnostic platforms
- Qualpro Diagnostics:** Virology and emerging infectious diseases
- Zephyr Biomedicals:** Virology and emerging infectious diseases
- Coral Clinical Systems:** Clinical and analytical reagents
- Tulip Marketing:** Import and export of diagnostic reagents and kits
- Crest Biosystems:** Clinical biochemistry reagents and instrumentation
- Lilac Medicare:** Immunoassays, clinical chemistry, research diagnostics

Diagnova

Spun off from Ranbaxy Fine Chemicals Limited, Mumbai-based Diagnova posted growth of 30.6% in 2004, beating the overall market growth rate of 18%. The company offers diagnostic reagents and instruments. Among its customer base of approximately 5,000 are pathology laboratories, private and public hospitals, nursing homes, blood banks, research facilities, and physician office labs.

Source: DTTR

Ranbaxy has spun off its diagnostic business. The company that is now called Diagnostics lost the Dade Behring agency, but still represents 14 IVD companies and manufactures chemistry tests.

Who are the top international IVD companies doing business in India?

McEvoy: We have been very impressed with the success of bioMérieux in India. They are the leader in the high-value immunochemistry market segment.

Roche and Hitachi are the leaders in India's chemistry markets. We expect them to become even stronger now that they are under their own control instead of being distributed by Nicholas Piramal.

Abbott, while not a major factor in chemistry or hematology testing, is expanding their presence in immunochemistry since they established their own office in Mumbai in 2003.

What's the potential for the Indian market?

McEvoy: Perhaps the most important aspect of India's demographics is the large number of Indians who live in rural settings, but who are migrating to cities. Almost 60% of India's citizens live in villages of less than 5,000. But the migration to urban settings can be seen in the growth of large cities. In 1991 there were 51 cities with more than half a million people, compared to only 36 in 1986. By 2010, one-third of India's population will be urban, up from just a quarter in the mid-90s.

India is experiencing two demographic trends that are important to the diagnostic market. First is the basic increase in the population seeking healthcare. Second is that rural Indians are much less likely to have access to modern healthcare than those living in cities. The shift to city life offers modern medicine and diagnostics to a population that is increasingly prosperous and able to pay for better care.

We expect to see the private sector portion of the market change with smaller laboratories coming under pressure from the rapidly expanding national chains. Dr. Ameera Shah, the marketing head for Mumbai-based Metropolis Laboratories, has been quoted in the local press as saying that consolidation is imminent. He said that their chain has been growing at 50%, while the other large laboratory groups were growing at about 25%. Most of this growth has come from expanded testing, particularly screening for lipid profiles, blood glucose, and glycosylated hemoglobin. But some of this growth is coming at the expense of smaller labs, a trend we expect to see continue as India evolves along much the same lines as other countries.

We have just finished our fifth study of India's IVD market in the last 10 years, and we have never been more optimistic. The market is growing between 15% and 20% per year, and we see no reason why this rate should not continue for the next decade. The need certainly exists, and with the economy surging forward, improved healthcare and enhanced diagnostics will continue to be a priority. 🏠

Molecular Testing Growth Steady At Boulder Hospital

While many labs are either touting their soaring molecular testing volumes or grumbling about molecular diagnostics as a “cost center,” Boulder Community Hospital Reference Laboratory has seen steady, if slow, growth in the eight years since it began offering molecular assays. This relatively small lab has succeeded with molecular testing by cautiously expanding their test menu, relying on kit-based assays, and keeping an eye on the bottom line.

The Boulder Community Hospital Reference Laboratory services Boulder Community Hospital and its two satellite hospitals. Among the three hospitals, they offer 305 licensed beds. The laboratory is also part of the Frontline Laboratory Network, which provides testing for affiliated members throughout Colorado.

The laboratory overall performs approximately \$1.1 million in billable procedures a year. Of those procedures, approximately 12,000 are molecular-based laboratory tests. The laboratory began offering molecular-based tests in 1998 on a limited basis. The first tests offered were for chlamydia and gonorrhea. They have since added HIV semi-quantitative tests, as well as HCV (hepatitis C virus) semi-quantitative, and human papilloma virus tests.

Lynel Vallier, the laboratory’s administrative director, notes that their affiliation with the Frontline Laboratory Network was one of the reasons they began offering molecular tests. “We became one of the providers of that test for the network. We had sufficient volume so it was financially feasible.”

Their growth for molecular-based tests has been steady, but not spectacular. They have no plans to increase the number and type of molecular-based tests, although their volume for their current test menu continues to increase.

Vallier notes that molecular testing is becoming simpler as the technology becomes more kit-oriented. “You don’t necessarily need dedicated rooms, although we do. We have one that that’s specifically dedicated to molecular testing.” All of their tests are kit-based and are semi-automated. Vallier says the molecular testing has proven profitable, but because they are a relatively small laboratory, everything must remain kit-based to be cost-effective.

The laboratory has approximately 105 total Full Time Equivalent (FTEs). Of those, 38 are medical technologists. Only four perform molecular testing. Originally they trained more, but have found that the more technologists they rotated through the molecular testing area, the more problems they had with consistency of technique and the consistency of results. 🏠

Boulder Community Reference Laboratory at a Glance

- ❑ \$1.1 million in annual laboratory billable procedures
- ❑ 105 FTEs
- ❑ 38 medical technologists/technical staff
- ❑ Performs 7,000 to 12,000 molecular tests annually

False-Positive Newborn Screens Can Have Devastating Effects

According to the CDC, over 4 million babies born in the U.S. each year undergo screening for biochemical genetic disorders, with severe disorders detected in about 3,000. One recent study suggests that there are at least 12 false-positive results for every true case diagnosed; another puts the ratio at more than 50:1.

As more disorders are added to the routine “heel stick” tests used to identify as many as 30 rare metabolic disorders in newborns, false-positive results are becoming more prevalent. A study recently published in the journal *Pediatrics* found that these false-positive results cause considerable parental stress, even if a negative result is obtained upon retesting, and that the stress could be alleviated by better education for parents and pediatricians.

The Children’s Hospital Boston research team interviewed 173 families who had received false-positive screening results and an additional 67 families with normal newborn screening results.

Mothers in the false-positive group (interviewed at least six months after receiving the false-positive result) reported more worry about their child’s future and rated themselves less healthy than mothers in the control group. Fifteen percent said their child needed extra parental care, compared to 3% of mothers in the control group. Both mothers and fathers in the false-positive group had higher scores on the standardized Parenting Stress Index.

Improved and better-timed education may reduce parental stress related to newborn screening, the study suggests. “There needs to be a specific communication plan for informing parents at every step,” said Elizabeth Gurian, a co-author of the study. “Currently, pediatricians are the primary distributors of this information, but some pediatricians don’t feel knowledgeable enough about these rare metabolic disorders to explain a positive test to a parent.” 🏠

Invitrogen To Collaborate On Proteomics Standards And Products

Invitrogen (Carlsbad, CA) recently announced that it will collaborate with the Human Proteome Organization (HUPO), an international consortium of proteomics research associations, government researchers, academic institutions, and industry partners, to advance proteomic research through education initiatives, standardization of research protocols, and development of advanced proteomic products. Financial terms of the collaboration were not disclosed.

“By improving education, training, and technology development, our organization can provide scientists the ability to better understand critically important areas of research,” said Gregory T. Lucier, Invitrogen’s chairman and CEO.

Through collaborations with protein laboratories around the world, Invitrogen and HUPO plan to develop a set of industry standards to enable large-scale data generation and analysis. HUPO’s Education and Training Initiative offers programs to promote expertise in all areas of proteomics, including sample preparation, protein separation, mass spectrometry, bioinformatics, and experimental design. “The potential for improving the effectiveness of proteomics research is an extremely exciting part of our collaboration with HUPO,” said Norrie Russell Ph.D., chief scientific officer for Invitrogen.

Invitrogen’s proteomics technology portfolio currently includes the Zoom Benchtop Proteomics fractionation and electrophoresis products, and its ProtoArray protein microarray. The company employs approximately 4,800 people globally and had revenues of more than \$1.2 billion in 2005. 🏠

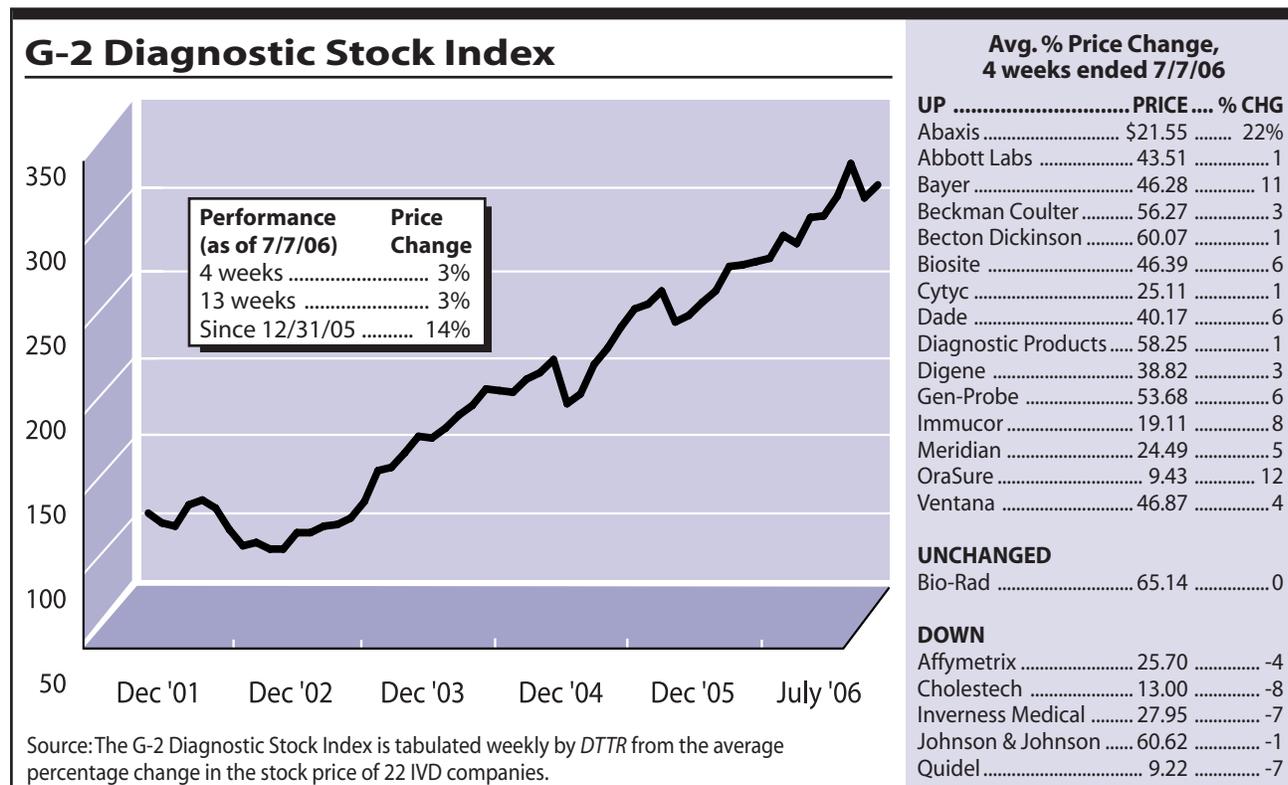
IVD Stocks Rise 3%; Abaxis Up 22%

The 22 stocks in the G-2 Diagnostic Stock Index rose an unweighted average of 3% in the four weeks ended July 7, with 15 stocks up in price, one unchanged, and six down. Year to date, the G-2 Index is up 14%.

Abaxis (Union City, CA) jumped 22% to \$17.71 per share for a market cap of \$392 million. The rebound can be attributed to the point-of-care blood test maker's recent announcement that it has entered an agreement with Henry Schein (Melville, NY), the largest distributor of healthcare products and services to office-based practitioners in the combined North American and European markets. Schein will distribute Abaxis's line of human reagent rotors and its Piccolo chemistry analyzer within the United States. Abaxis recently discontinued its agreement with Schein for veterinary products distribution, a channel that accounted for about 14% of Abaxis's total business for the most recent fiscal year.

Things were also looking up at **OraSure** (Bethlehem, PA). Shares in the immunoassay manufacturer were up 12% to \$9.43 per share for a market cap of \$391 million. The stock rose on the news that the New York City Department of Health has agreed to buy \$6 million in rapid HIV tests. The multiyear agreement calls for OraSure to supply OraQuick Advance rapid antibody tests, which use saliva to detect the presence of HIV-1 and HIV-2 in 20 minutes.

Meanwhile, shares of **Cholestech** (Hayward, CA) were down 8% in the four-week period to \$13.00 per share for a market cap of \$186 million. ▲



G-2 Insider

'Tis the season for Lyme Disease and hantavirus . . . This year, experts are predicting more widespread outbreaks of Lyme disease and hantavirus, two conditions for which early diagnosis is critical.

Lyme disease is on the rise. In 2005, reported cases of the disease increased by 34% in Connecticut (to 1,810 cases) and 23% in New Jersey (3,372 cases). The disease is most prevalent in Eastern and Midwestern states. Blood tests alone cannot diagnose Lyme disease, but they are used to confirm a diagnosis. ELISAs are the most commonly ordered tests for Lyme disease, with Western blots used as a follow-up.

Hantavirus outbreaks could also be on the upswing, at least in certain states, according to a recently published study funded by the joint National Science Foundation-National Institutes of Health Ecology of Infectious Disease program. Researchers analyzed satellite imagery to pinpoint regions at the greatest risk for an outbreak of hantavirus, which is transmitted through contact with rodents and can cause a rare but deadly respiratory disease.

"The conditions in the Four Corners region [where Arizona, New Mexico, Colorado, and Utah meet] tell us that there is a greater risk for hantavirus this year compared to last year," said Gregory Glass, Ph.D., of John Hopkins University, the study's lead author. In 2005, the Four Corners region recorded four cases of hantavirus. This year, the researchers forecast the hantavirus risk to be "moderate," similar in severity to the six and eight cases recorded in the region in 1998 and 1999, respectively. 🏠

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