



Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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Established 1979

The Direct-Access-Testing Money Pit

Over the past several years, a number of hospitals, commercial labs, and website companies have started marketing lab tests directly to consumers. These “direct-access-testing (DAT)” programs allow consumers to order and pay for their own lab tests. Glowing articles in the *New York Times*, *Wall Street Journal*, *Washington Post*, etc., have described a “paradigm shift” where individuals are increasingly taking charge of their own health.

But this editor’s visit to a Quest Diagnostics’ DAT center plus candid interviews with 10 DAT program executives suggest that consumers have shown little interest to date in buying their own lab tests. Most DAT ventures have turned out to be expensive and time-consuming flops that attract few customers.

Even the more successful DAT companies are struggling. Direct Laboratory Services (Mandeville, LA), which markets tests through its website (*Directlab.com*), attracts 500 self-paying customers each month, according to John Bell, president. But he says that after paying for contracted laboratory services from LabCorp and LabOne, advertising expenses, and employee salaries, there is nothing left over. “A lot of companies are spending a lot of money trying to find out what works and what doesn’t work in this business. I never worry about the competition because they generally don’t last long,” he says. For more plain talk on DAT, see *Inside the Diagnostics Industry*, pp. 5-9. 🏠

Will All U.S. Cattle Eventually Be Screened For Mad Cow?

The U.S. Department of Agriculture (USDA) has announced plans to dramatically expand its mad-cow surveillance program using rapid tests made by Bio-Rad, Idexx Laboratories, and possibly other vendors. The move comes after a cow in Mabton, Washington tested positive in December, and the USDA was criticized for testing too few cattle (see *DTTR*, February 2004, pp. 1-2). Under the expanded program, an estimated 300,000 U.S. cattle will be tested for mad cow. That’s more than the total number of mad-cow tests that have been performed throughout the United States for the past 10 years.

DTTR speculates that if more positive cows are found, public pressure may build to test all 35 million U.S. cattle that are slaughtered for the food supply each year. Under this scenario, the U.S. market for mad-cow tests could reach as high as \$350 million per year (35 million tests x \$10 per test). And, if and when a blood test is developed, the human blood supply could one day be screened for the deadly disease as well. ➡ p. 2

Cattle get mad-cow disease, formally known as bovine spongiform encephalopathy (BSE), by eating other cattle. Ground-up cow carcasses were commonly fed to cattle as an inexpensive protein source beginning in the 1980s. The U.S. and Canada banned the practice in 1997 after discovering it spread the disease.

▲ **Mad Cow**, from page 1

On March 15, the USDA announced a one-time program designed to inform the agency whether or not the positive cow found in Washington was an isolated case. The program, which is to begin June 1 and last for 12 to 18 months, will target cattle that are most prone to mad cow. The targeted population will include cattle that are too weak to walk, exhibit a nervous system disorder, or are found dead on farms. The USDA estimates that this group of animals is approximately 446,000 on an annual basis. In addition, the USDA plans to test a sample of approximately 40,000 healthy cattle that are over 30 months old.

In conjunction with the program, the USDA has licensed rapid tests made by Bio-Rad Laboratories (Hercules, CA) and Idexx Laboratories (Westbrook, ME). The license allows both companies to sell their mad-cow tests to the USDA's main laboratory facility in Iowa as well as to a network of some 24 state and university laboratories that the USDA plans to certify to handle the increased testing. Labs that are expected to be part of the network include veterinary labs at Colorado State University, the University of Nebraska, and the University of California at Davis.

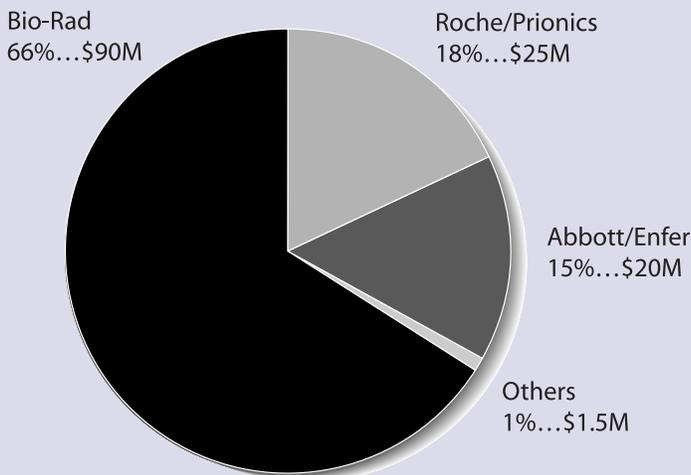
The rapid mad-cow tests take about four hours to complete after specimens are delivered to the laboratory. All positive results will be sent to the Iowa lab for confirmation, using a traditional immunohistochemistry method, which has a turnaround time of four or more days.

Brad Crutchfield, vice president of life science at Bio-Rad, estimates that the USDA and its network will be able to obtain specimens and test roughly 300,000 cattle out of the targeted population of 486,000. Bio-Rad and Idexx, the only two mad-cow test makers currently approved by the USDA, sell their mad-cow tests for about

\$10 each, so the potential market for this one-time effort is only an estimated \$3 million (300,000 tests x \$10).

The Worldwide Market for Mad-Cow Tests

Last year an estimated 13 million mad-cow tests were sold worldwide at an average price of \$10.50 per test for a market size of \$136.5 million. Most of the testing is performed in Europe and Japan, where government-mandated screening programs are in place.



Source: DTTR estimates

But DTTR speculates that public pressure could build for a permanent large-scale testing program if more cattle test positive. On a March 15 conference call with reporters, the USDA's chief veterinarian, Ron DeHaven, D.V.M., said, "We believe that the prevalence of BSE in the country, based on more than a decade of sampling that's already been done—if it exists at all—is extremely low. Nonetheless, there is, and I think we need to recognize that there is, a chance that we could find more positive cattle."

Meanwhile, the USDA's strict control of all mad-cow testing in the United States is being challenged on two fronts. First, two California politicians have introduced a

Since 1995 at least 155 worldwide deaths (mostly in Britain) have occurred from vCJD, the human equivalent of mad-cow disease. Humans get the disease, which causes holes in the brain, by eating infected beef. There is no treatment or cure.

bill (SB 1425) that would require all beef and beef-based meat products sold or processed in the state to come from cattle that have tested negative for the disease.

In addition, Creekstone Farms (Arkansas City, KS), a privately held meatpacking company, has announced plans to voluntarily test every animal processed at its Kansas plant for mad-cow disease in order to satisfy concerns from its import customers. More than 40 countries, including top U.S. beef importer Japan, have banned U.S. beef since December. Japan, which imports about \$1.8 billion of American beef each year, tests all of its domestic cattle for mad cow at slaughter. Japanese officials have repeatedly stated that they will not buy U.S. beef until the United States does the same.

Currently, the USDA's lab in Iowa is the only facility in the entire United States that performs mad-cow tests. And the agency's licenses with Bio-Rad and Idexx forbid each company from selling their mad-cow tests to anyone other than the USDA or a certified state or university lab. On the conference call, DeHaven said that the USDA was evaluating proposals to allow private testing for mad cow, but he offered no timetable for a decision.

Finally, *DTTR* notes that several IVD companies are trying to develop a blood test for mad cow that can be performed on live animals. The current methods for both the rapid tests and IHC test require a sample of a dead cow's brain for testing. Crutchfield believes that development of a blood test for mad cow, or its human equivalent (variant Creutzfeldt-Jakob Disease-vCJD), is at least two to three years away. Concern that vCJD could spread through the blood banking system was underscored in December when the British government announced the first reported case of a person dying from the disease after a blood transfusion from an infected donor. 🏠

LabCorp Launches New Liver Test: HCV FibroSure

LabCorp says that some portion of the 2.7 million Americans chronically infected with HCV are candidates for the HCV FibroSure test.

LabCorp (Burlington, NC) has begun marketing HCV FibroSure, a blood test for assessing liver status in hepatitis C virus (HCV) patients, at a list price of \$300 per test. The test was developed by hepatologists at the Pitie-Salpetriere Hospital (Paris) and BioPredictive (Houilles, France), a privately held diagnostic test developer, and has been available in Europe for the past two years. LabCorp holds an exclusive license to market the test in the United States.

LabCorp is marketing HCV FibroSure as an alternative to liver biopsy, which physicians use to assess liver fibrosis and necroinflammatory activity in HCV patients. While liver biopsy has long been considered the gold standard to monitor the status of HCV and determine therapy options, it is an invasive procedure that carries a risk of serious complications.

HCV FibroSure uses a combination of six existing tests—alpha2-macroglobulin, haptoglobin, apolipoprotein A1, total bilirubin, gamma glutamyl transpeptidase, and ALT—plus age and gender information in a patented algorithm. These six tests are currently covered by Medicare on an individual basis and have a combined reimbursement of \$83. 🏠

Can Abaxis Succeed Where Careside Failed?

Abaxis submitted a request to the FDA for CLIA-waiver status for its Piccolo lipid panel in December 2003.

Over the past 10 years, Abaxis (Union City, CA) has built up a profitable business of selling portable analyzers and reagent cartridges to the veterinary market under the brand names VetScan (for blood chemistry) and VetScan HMT (for hematology). For example, in the nine months that ended Dec. 31, 2003, the company generated \$27.3 million from the veterinary market, up 27% from \$21.6 million in the same period a year earlier.

Now the company is targeting the human diagnostics market. About a year ago, Abaxis hired Ron Blazik as director of marketing along with six sales reps and an area director to drive sales of the company's Piccolo blood chemistry analyzer for the human diagnostics market.

The Piccolo is basically a version of its VetScan analyzer with a test menu geared toward human diagnostics. The instrument weighs 6.9 kilograms and has a test menu of 11 panels with a combined 25 analytes that have been cleared for use at CLIA-licensed labs. Test results from whole blood are provided in less than 15 minutes.

The list price for the Piccolo is \$17,000, and the average selling price per test cartridge panel is about \$10. Panels include general chemistry (12 tests), liver panel (8 tests), comprehensive metabolic (14 tests), and lipid panel (3 tests and 3 calculated values).

But selling chemistry analyzers into the physician office market has been a tough row to hoe. Just look at Careside, which burned through \$71 million over the course of six years while trying to sell its chemistry analyzer to physician offices and then filed for bankruptcy in October 2002.

Why will Abaxis succeed? Blazik offered *DTTR* several answers. Number one, he says, Abaxis already has \$16 million in the bank and a profitable veterinary business that can sustain its expansion into the human diagnostics market. And Blazik says that the company is taking a measured approach to its marketing strategy and plans to add two sales reps per quarter as its revenue grows. Finally, he says that the Abaxis instruments have proven they function properly. He notes that the company has placed about 5,000 VetScan systems in the United States and more than 300 Piccolos are being used by the U.S. military (the initial human diagnostics market for Abaxis).

About 150 Piccolos have been placed in non-military sites (small hospitals, oncology clinics, and physician offices), with most of the placements occurring within

the past 12 months. Blazik says the typical non-military client performs between 5 and 12 test panels per day. He notes that the average \$10 cartridge price works out to be approximately 90 cents per reportable test result and includes the cost of calibrators and controls. He says that the Piccolo comes with a software program that walks lab techs through new CLIA regulations that requires physician-office labs to validate manufacturers' performance claims for non-waived tests they add to their menus. 🏠

Abaxis at a Glance (\$000)

	9 mos. ended 12/31/2003	9 mos. ended 12/31/02	Change
Revenue	\$34,129	\$24,604	39%
human diagnostics	5,294	1,869	183
veterinary	27,305	21,574	27
other	1,530	1,161	32
Net income	2,683	-260	NA
Cash	16,048	10,430	54
Long-term debt	117	466	-75

Source: Abaxis

Everything You Need To Know About Direct-Access Testing

Despite all the positive articles in the popular press and most trade publications, the consumer demand for direct-access testing is not yet there.

Over the past few years, dozens of traditional hospital and independent laboratories as well as new website companies have tried their hand at marketing lab tests directly to consumers. The idea of selling “health profile” panel tests at \$90 to \$120 each and getting paid upfront by cash or credit card is alluring.

But instead of becoming a cash cow used to supplement traditional hospital outreach or independent lab business, every DAT program that *DTTR* is aware of is a money-losing venture that distracts labs from their core business of serving hospital inpatients and physician offices. Those DAT programs that do manage to attract more than a couple customers per week must spend heavily on TV, radio, newspaper, or Internet advertising, which can put them deeper in the hole.

The typical scenario is that a hospital or independent lab will launch a DAT program that generates a lot of free press in the local newspapers and talk of a “new age” or “paradigm” in health care. Debate over the ethics of allowing consumers to manage their own health care soon follows. But it’s all moot because hardly anyone is buying lab tests through these programs.

For a closer view, *DTTR* contacted 10 different DAT ventures around the country. Here’s what we found out:

Marketing DAT in Grocery Stores—A Reporter’s Experience with QuesTest

To help increase visibility and attract customers, some commercial labs and hospitals are marketing DAT in grocery stores. In mid-2003, Quest Diagnostics signed a deal with the Stop & Shop Supermarket Company (Quincy, MA) that allowed it to place DAT advertising stands in the pharmacy sections at 60 Stop & Shop stores in Connecticut.

Your editor lives in upstate New York and to get a firsthand view of how this program works, I recently took a 30-minute drive to a Stop & Shop store in Danbury, Connecticut, to buy a test. The “QuesTest” display stand was located near the cash register at the pharmacy section of the store and was stocked with about a dozen different 3-by-6 inch plastic test cards to choose from, including a Men’s Health Profile (cholesterol, triglycerides, iron, kidney function, liver function, glucose, and thyroid function) priced at \$115, a hepatitis C test at \$50, and prostate specific antigen (PSA) at \$45. I picked up a Heart Rick Panel card (total cholesterol, HDL, LDL, and triglycerides) priced at \$40 and used my debit card to pay for it.

I asked the pharmacist at the counter if he could tell me how many people were buying tests each week. “A couple. But this is a new service. People aren’t used to buying their own lab tests,” he said.

After purchasing my test card, I drove home and called the phone number on the back of the card to get a confirmation number and locate a Quest patient service center (PSC) where I could get my blood drawn. The friendly and profes-

A Quest spokes-
woman tells
DTTR that the
company's DAT
initiatives have
not generated
significant
revenues to date.

sional woman I spoke with helped me locate the nearest PSC. Although I bought the test in Connecticut, I was told I could go to a PSC in New York and didn't need an appointment. I double-checked the QuesTest website, which also indicated I could go to a PSC in New York.

But a few days later when I showed up at the chosen PSC with my QuesTest card and confirmation number, the staff had no idea how to register me. After a series of calls back and forth between the PSC staff and their offsite manager, I was politely told that I need to have my blood drawn at a PSC in Connecticut.

So a few days later I drove back to Connecticut to get my blood drawn at a Quest PSC. This time everything went smoothly and I was in and out of the PSC in 15 minutes. However, the phlebotomist did mention that I was the first QuesTest customer to ever get their blood drawn at this particular location. That's pretty amazing given that Quest has been marketing this service at 60 supermarkets in Connecticut for almost a year now.

The QuesTest website and marketing brochures promise customers that they can get their test results online 48 hours after having their blood drawn. However, I had my blood drawn on the morning of April 1 and my results were not available online until the afternoon of April 6 (my test results, by the way, showed I had a high total cholesterol value of 218 and a high LDL of 134).

Meanwhile, *DTTR* notes that Quest had tried a similar partnership with CVS drugstores in Ohio in mid-2002, but it was shut down less than a year later because of poor consumer response. Shortly thereafter, Ohio State University Medical Center (OSU—Columbus) began marketing a limited menu of lab tests to consumers at the pharmacy sections at 40 Kroger supermarkets in the greater Columbus area. Kroger is one of the largest grocery store chains in the country.

The program, dubbed "The OSU Lab Test," allows consumers to prepay for eight different tests and panels at Kroger pharmacies and then phone one of six OSU clinics to schedule an appointment to have their blood drawn. Amy Gewirtz, M.D., medical director of the OSU lab, had hoped that OSU's local name recognition would help it succeed where Quest had failed.

So what's the customer volume like after about a year on the market? Gewirtz would not answer this question. But she did note that one of the challenges was the fact that the program was not one-stop shopping: Consumers have to make a trip to a grocery store to buy a test, then schedule an appointment and drive to a PSC center, and then wait a few days to receive their test results. For those labs thinking about starting up a similar program, she advises, "If you think this is going to turn your company around, you are wrong."

Gewirtz believes that onsite phlebotomists who could draw patient/customer blood right after they purchase a test might improve demand. US Wellness (Gaithersburg, MD), a privately held company that manages health screening programs, tried this idea in the pharmacy departments at 10 Giant Food Supermarkets in Maryland and Virginia early last year. Each of the 10 sites was staffed by a nurse or physician assistant employed by US Wellness to draw specimens.

But this was expensive, and consumer demand was so weak that the program was scrapped after a few months. "What we learned is that when people go to the grocery store, they are thinking about buying food, not lab tests," Tori Tomlinson, co-president of US Wellness told *DTTR*.

Marketing Lab Tests through a Website

Selling lab tests through a website is a low-overhead way to reach a national audience of potential customers. Numerous entrepreneurs have signed contracts with either Quest, LabCorp, or LabOne to handle the actual testing, while they market tests through their websites and get paid by credit card. Most of them are fly-by-night companies that quickly go out of business.

Among the lab websites that tried, failed, and went out of business are *HealthTesting.com*, *HealthDirector.com*, *EHIV.com*, and *CompleteBloodwork.com*.

Among the few website marketers that have survived is Direct Laboratory Services (mentioned on page 1), which was founded by its president, John Bell, in 1990. From day one, Bell says it has been a constant battle to pay the bills. He says that DLS would have gone out of business a long time ago if not for the income from a separate PPO network that the company operates.

DLS markets lab tests on its website and spends most of its advertising budget (a few thousand dollars per month) on search engines. For example, if you search for "lab test" on Google, a link to the DLS website will appear on the right-hand side of the page.

Bell says that the company's most frequently ordered test is a "Comprehensive Wellness Profile" that is priced at \$89 and includes a thyroid profile, lipid panel, liver panel, blood glucose, electrolytes, iron, calcium, and phosphorus. Customers order and pay for the tests at the website or by phone and then must go to a LabCorp or LabOne PSC to have their blood drawn. Results are available in a few days online or by mail.

Bell says he's been involved with DAT in one form or another for the past 20 years, including onsite testing ventures at health clubs, pharmacies, and supermarkets. He says the number-one challenge is convincing consumers that they must take charge of their own health. When will DAT catch on in the United States? "Probably not in my lifetime," says Bell who is age 59.

Do Stand-Alone Retail Lab Stores Work?

The simple answer is no. Quest tried this strategy in early 2001, when it opened six retail lab locations at strip shopping malls in various markets in the Midwest. These lab stores were aimed at attracting consumers to walk in and order a lab test on their own and then pay by cash or credit card. However, low demand for the service led Quest to shut down all of its DAT retail centers in 2002.

Another company that has learned the difficulties of the retail approach is HealthScreen America (Jacksonville, FL). It opened a 9,000 square-foot retail health screening facility in Jacksonville in January 2000 that offered a combination of diagnostic imaging and lab testing services to walk-in customers. Screening packages were priced as high as \$2,295 for a combination of 30 lab tests and a full body CT (computed tomography) scan.

But even after spending \$26 million raised from a group of investors on equip-

Sioux Valley Clinical Laboratories has made a big investment in its DAT retail store and related advertising. Can the venture attract enough customers to cover its costs? Initial results look promising, but it's too early to tell.

ment, advertising, and a payroll of 90 employees, HealthScreen America was never able to generate enough demand. In March 2002, after only about two years of operation, the company ran out of money and was forced to close its doors.

Early this year, another group of investors took over what was left of the company and opened a new HealthScreen America center in Buckhead, Georgia (an affluent suburb of Atlanta). Beth Doty, vice president of operations, tells *DTTR* that the company is now taking a much more conservative approach to the business. For example, the new center is only 4,000 square-feet and the company has a total of just 17 employees.

Doty says that HealthScreen America is now marketing its services to a broader range of customers and has started accepting payment from health insurance companies. She says that there's not enough demand from the retail customer market, so the company is also seeking contracts with employers to provide health screening benefits. The company is also seeking more traditional lab testing business from local physician offices.

Meanwhile, Sioux Valley Clinical Laboratories (SVCL) in South Dakota has jumped into direct access testing with both feet. In November 2003, the hospital lab opened a retail store dubbed "DirectTEST" in the Empire Mall (Sioux Valley), which is one of the largest malls in the Midwest. The store offers a wide test menu, including allergy panels, thyroid panels, mono and strep screens, and cancer tests (e.g., AFP tumor marker, CA 15-3, CEA, etc.), and staffs a phlebotomist. In addition to the visibility provided at the mall, DirectTEST is being advertised on local TV, newspapers, and through direct mail. SVCL is also marketing DirectTEST to local physicians to get referrals for uninsured patients. SVCL executives interviewed by *DTTR* would not disclose exact test volumes for DirectTEST, although they hinted that the store was attracting a few hundred paying customers per month and growing. The most popular tests are PSA, priced at \$40; lipid panel for \$32; and Men's Health Panel for \$164.

DAT Efforts at Two Independent Labs

David Carrozza, president of The Lab (Folsom, CA), an independent lab with 15 PSCs and 40 employees, has been marketing DAT services in the Sacramento area for more than 10 years. Even so, he says that DAT makes up only 5% to 10% of his lab company's overall revenue of about \$3.5 million.

Carrozza says he consistently spends money on TV and radio advertising. He says DAT sales would dwindle without it. "Everyone knows Coca-Cola, but they never stop advertising," he notes. Although DAT is basically a breakeven business at best, Carrozza says he doesn't mind spending on it because it builds name recognition for The Lab, which helps his traditional physician-office service business.

He also says that because the purchase of preventive lab tests are a discretionary spending item for consumers, he keeps prices low. The Lab charges \$10 each for total cholesterol, blood pregnancy tests, and glucose; the full lipid panel costs \$35.

Finally, Carrozza advises other labs thinking about starting a DAT program not

Quentin Medical Lab has done some advertising in local newspapers and at its PSCs and gets a few DAT customers each week.

to have overly optimistic expectations. "The time when you can build a business model around self-directed testing just isn't there yet," he says.

On the other side of the coast, Hal Rose, president of Quentin Medical Lab (Brooklyn, NY), says his DAT program has also seen limited demand. Rose launched the program in late 2002, right after New York State passed a law allowing consumers to order tests without a doctor's prescription for any analyte approved by the FDA for over-the-counter sale.

"People generally have enough access to physicians when they need a lab test, and buying pregnancy tests and drugs-of-abuse tests in a drugstore is more anonymous. As long as patients have access to their doctors, demand for direct-access testing will be limited," says Rose. "Don't invest too much money or time in it [DAT], but don't throw it out the window either," he advises.

An Urgent Need to Know Drives Consumer Purchases of Lab Tests

Question: *What does it take to get consumers to spend their own money to buy a lab test?*

Answer: A sense of urgency!

Everyone knows that sales of pregnancy tests at pharmacies and supermarkets are a hot selling item. Some \$200 million worth of at-home pregnancy tests are sold by retailers each year in the United States. Women are willing to shell out the \$10 that these tests cost because they have a desire to know the answer right away. For most women, a positive result is a cause for celebration that allows them to start planning for a new baby, while for others, a positive result can be unexpected bad news that may require a difficult choice. But either way, there is an urgency that drives each purchase of an at-home pregnancy test. The ease-of-use, rapid test result, and low cost also help drive the sale of these tests.

Over the past eight years, consumer demand for infectious disease testing has also become well established. In 1996, Home Access Health (Hoffman Estates, IL) gained FDA clearance to sell its HIV at-home sample collection kit to consumers. In 1999, the company gained clearance for its hepatitis C at-home kit.

Since then, Home Access has established a solid business for direct-to-consumer sales of its tests via phone, Internet, and traditional retail stores. Joe Smith, vice president of development, says the company is currently selling about 65,000 HIV tests and 50,000 hepatitis C tests per year. Annual revenue is about \$5 million, and the company is nearing profitability, says Smith.

Home Access has the only FDA approved at-home sample collection devices for HIV and hepatitis C.

Home Access test kits are used to collect a sample of blood, which is then mailed to the company's CLIA-certified laboratory in Illinois. All test orders are reviewed by Home Access's medical director, Allan Frank, M.D. Results are provided via phone or the Internet through the use of a pass code. The company's HIV tests retail for \$44 (one-week turnaround) or \$60 (three-day turnaround); hepatitis C sells for \$50 per test. New tests that Home Access is now marketing include total cholesterol, at \$15, and an allergy panel, at \$70.

Smith says it's the urgency and importance of finding out whether you have HIV or hepatitis combined with the anonymity of purchasing a test from Home Access that have driven consumer demand. Home Access never reveals the test results to anyone except to each individual customer. 🏠

Worldwide IVD Sales Grew 5% In 2003 To Reach \$24 Billion

Worldwide IVD sales were up 5% to \$23.8 billion last year, according to an exclusive analysis by *DTTR* of financial reports from the 12 largest reagent manufacturers. Our estimate assumes that the 12 largest companies held an 85% share of the market with the remaining 15% held by hundreds of smaller companies.

Roche Diagnostics (Basel, Switzerland) remains the largest IVD company with 22% market share. The company reported \$5.3 billion of revenue in 2003, up 10% (excluding foreign exchange fluctuations). Roche's fastest-growing diagnostics business area was molecular diagnostics, which grew by 21% to \$702 million.

Cytec Corp. (Boxborough, MA) was the fastest-growing major IVD company, with a 28% increase in revenue to \$303 million. Next was **Diagnostic Products Corp.** (Los Angeles), which grew by 11% to \$381 million.

The only big IVD company to record declining sales was **Abbott Diagnostics** (Abbott Park, IL), which reported \$3 billion in revenue, down 2%. The biggest decline came in Abbott's U.S. diagnostic sales, which fell 12% to \$1 billion; international sales were up 5% to \$2 billion.

The most important macro development for the largest IVD makers in 2003 was the slowdown in the glucose monitoring business. Based on financial reports from the five largest vendors (Roche, Lifescan, Bayer, Medisense, and TheraSense), *DTTR* calculates that this market grew by only 4%, to approximately \$5 billion. This compares with annual growth that had averaged better than 10% for the previous three years. 🏠

Top 12 IVD Manufacturers' Worldwide Revenue (\$ millions)

Company	2003 Revenue	2002 Revenue	Unadjusted % Chg	Excl. exchange rate fluctuations % Chg	2003 Market Share
Roche Diagnostics ¹	\$5,294	\$5,053	5%	10%	22%
Abbott Diagnostics	3,040	2,897	5%	-2%	13%
Johnson & Johnson	2,602	2,436	7%	1%	11%
Bayer Diagnostics ²	2,358	2,488	-5%	5%	10%
Beckman Coulter	1,541	1,418	9%	5%	6%
Dade Behring	1,436	1,282	12%	5%	6%
Biomerieux ³	1,110	1,145	-3%	5%	5%
Becton Dickinson ⁴	999	894	12%	7%	4%
Symex ⁵	619	538	15%	NA	3%
Bio-Rad Labs	515	455	13%	5%	2%
Diagnostic Products	381	324	18%	11%	2%
Cytec Corp.	303	237	28%	28%	1%
Top 12 total	20,199	19,166	5%	5%	85%
Other IVD companies	3,565	3,382	5%	5%	15%
Total IVD Market	\$23,764	\$22,548	5%	5%	100%

(1) Roche revenue is based on exchange rate of \$1 USD=1.27 Swiss franc. (2) Bayer revenue is based on exchange rate of \$1 USD=0.82 euros. (3) Biomerieux revenue is based on exchange rate of \$1 USD=0.82 euros. (4) Includes diagnostic systems and flow cytometry. (5) Symex revenue is based on exchange rate of \$1 USD=106 Yen.

Source: *DTTR* from company financial reports

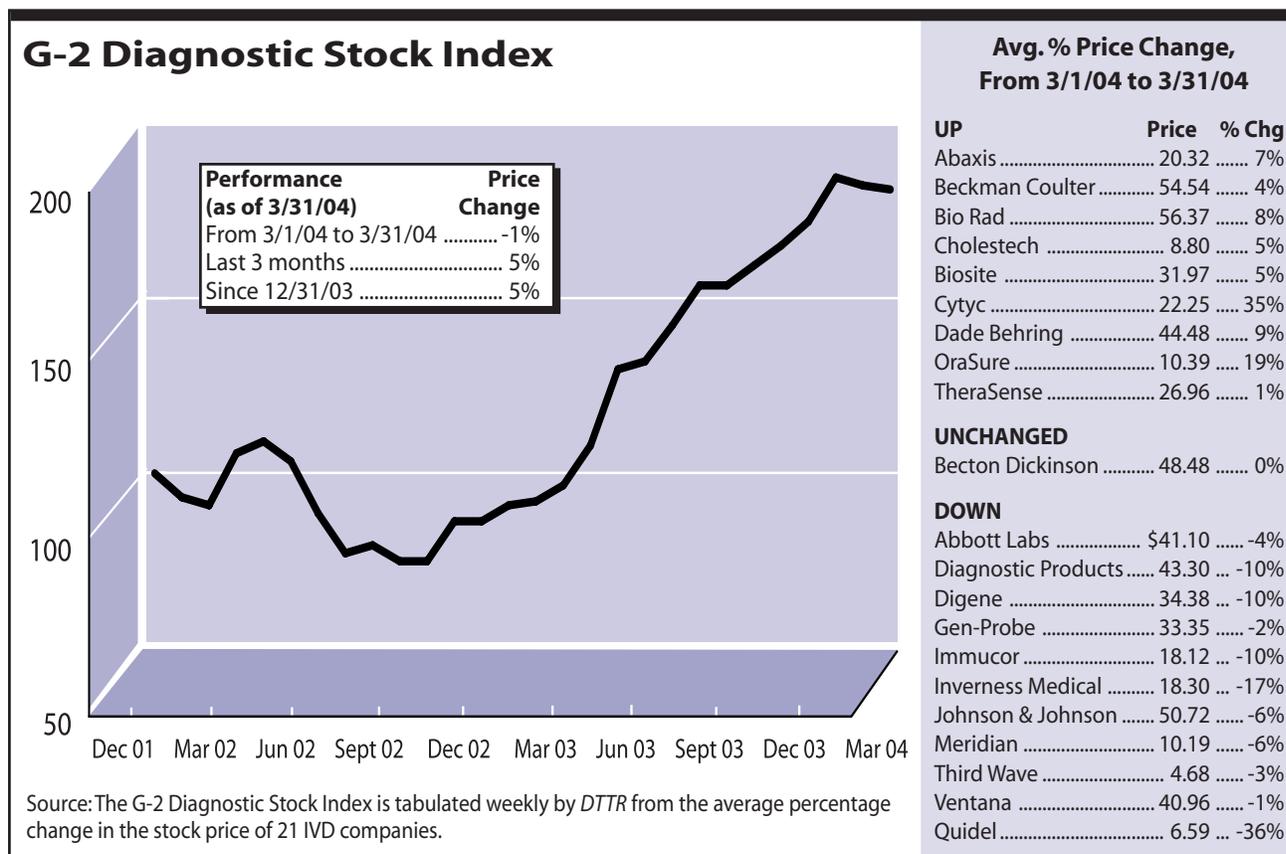
IVD Stocks Slipped 1% In March

The 21 stocks in the G-2 Diagnostic Stock Index fell an unweighted average of 1% in the month of March, with 11 stocks down in price, one unchanged, and nine up. Year to date, the G-2 Index is up 5%, while the S&P 500 Index is up 1% and the Nasdaq is unchanged.

Among the gainers in March was OraSure Technologies (Bethlehem, PA), which rose 19% to \$10.39 per share for a market cap of \$460 million, which is more than 10 times the company's reported 2003 revenue of \$40.5 million. OraSure was boosted on news that the FDA had approved its rapid saliva test for HIV-1. Company spokesman Bill Bruckner says the test, named OraQuick, will sell at an average price of about \$10 to \$12. He says OraSure will seek a CLIA waiver for the test.

OraSure has had an FDA-cleared, CLIA-waived, rapid HIV-1 blood test on the market for more than a year. Bruckner estimates that there are a total of approximately 16.5 million HIV-1 tests performed in the United States each year (excluding blood banking). This estimate includes 12 million tests at hospitals, 2.5 million at public health centers, and one million each at physician-office labs and the military.

Meanwhile, Cytoc Corp. (Boxborough, MA) jumped 35% to \$22.25 per share for a market cap of \$2.4 billion on news that it was acquiring medical-device-maker Novacept (see *DTTR*, April 2004, p. 1-2). 🏠



G-2 Insider

It's silly season again. Proxy statements detailing the executive compensation at the nation's publicly traded companies are beginning to be filed with the Securities & Exchange Commission. And, like all other big public companies, chief executive pay at the largest IVD firms is over the top.

In the next issue of *DTTR* we plan to provide our usual full rundown of salary, bonus, and option awards for the CEOs at the top 20 or so publicly traded IVD companies. In the meantime, here's a quick preview: Miles White, age 48, chairman and CEO of Abbott Laboratories, earned a grand total of \$9 million, including a salary of \$1.56 million, up 4.5% from 2002; bonus of \$1.75 million, up 40%; stock options worth \$5.54 million; and "other" compensation (i.e., perks) worth \$162,370.

William Weldon, 55, chairman and CEO of Johnson & Johnson, got \$8.7 million, including a salary of \$1.27 million, up 15%; bonus of \$1.95 million, up 61%; stock options worth \$4.26 million; and other compensation of \$1.25 million.

Jack Wareham, 62, chairman and CEO of Beckman Coulter, got \$7.8 million, including a salary of \$775,000, up 3%; bonus of \$706,880, up nearly 500%; restricted stock and options worth \$6.2 million; and other compensation of \$91,220.

Board compensation committees and pay consultants will argue that good CEOs are hard to find and worth every dime they are paid, but I'll bet if you offered the CEO job to the next three top executives at any public IVD company at a 30% pay cut, they'd each jump at the chance.

Think I'm all wrong? You can write me at labreporter@aol.com.

Jondavid Klipp, editor 

Company References

- Abaxis 510-675-6500
- Bio-Rad 510-724-7000
- Direct Laboratory Services
800-908-0000
- DirectTest 605-333-1000
- HealthScreen America
404-869-0054
- Home Access Health
847-781-2500
- LabCorp 336-584-5171
- OraSure 503-641-6115
- OSU Lab Test
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