Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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WASHINGTON G-2 REPORTS

Established 1979

Lab Execs Say Reagent Prices Are Stable, But Ask For Greater Instrument Reliabilty, Less Recalls

As business gets under way in the New Year, *Diagnostic Testing & Technology Report* interviewed the top executives at 10 large hospital and independent labs for their outlook for the lab industry in 2004 and what IVD manufacturers can do to help them succeed. Lab execs say reagent prices are rising by roughly 3%, but that's not their biggest concern. They tell *DTTR* that their top need is greater instrument reliability and fewer reagent recalls and back orders.

In addition, lab execs say that the consulting-type services offered by the big reagent vendors have been a big help in improving efficiency. And now labs say they'd like similar help in managing the financial aspects of running their outreach/commercial-testing businesses.

In terms of expanding test menus in the New Year, the most frequently cited tests included viral load and genotyping for HIV and hepatitis C, cystic fibrosis genetic analysis, and high-sensitivity CRP. To cope with the shrinking pool of medical technologists, labs say they are giving medical lab technicians and assistants greater responsibility so that MTs can focus their time at the bench.

For specific comments and opinions from the 10 lab execs interviewed, see *Inside The Diagnostics Industry*, pp. 5-9.

Reimbursement Cut Throws Monkey Wrench Into Emerging Field Of Automated Cell Imaging

The Centers for Medicare & Medicaid Services (CMS) has announced a new surgical pathology CPT code (88361) for cell-image analysis, effective Jan. 1, 2004. The new code is being reimbursed at a combined professional and technical component rate of $132. That's better than the $85 interim rate that image analysis had been reimbursed by Medicare between April 1 and Dec. 31, 2003. But it's a lot worse than the $200-plus that pathologists and labs were getting previously. The cut has sent manufacturers of automated cell-imaging systems, like ChromaVision (San Juan Capistrano, CA) and Applied Imaging Corp. (Santa Clara, CA), scrambling to renegotiate their contracts with customers at lower prices and could even put some vendors out of business for good.

Continued on p. 2

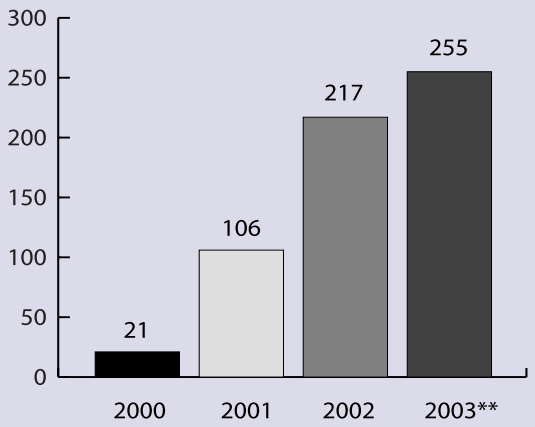
▲ **Reimbursement Cut,** *from page 1*

When this publication last highlighted ChromaVision and other cell-imaging system vendors (*see DTTR, March 2001, p. 1*), our view was that attractive reimbursement rates would lead to a boom in adoption. And that's what happened. Under the advice of vendors, pathologist and lab customers that performed Her-2/neu analysis using the new automated cell-imaging systems billed Medicare for CPT code 88358 plus the technical component of 88342 for total reimbursement of more than $200, versus only $80 if done under the traditional manual methods.

The attractive reimbursement allowed vendors to place hundreds of their cell-imaging systems in the field. For example, placements of ChromaVision's ACIS system have grown from 21 units at year-end 2000 to 255 units as of Sept. 30, 2003.

When Medicare reimbursement was more than $200 per Her-2/neu analysis using ACIS, ChromaVision had charged pathology groups and labs as much as $80 per test. But the new reimbursement of $132, including a technical component of approximately $80 and a professional component of $52, means that ChromaVision and other cell-imaging systems vendors will need to drastically reduce their prices or face a slew of system returns and cancellations.

ChromaVision ACIS Placements*



*Includes ACIS systems and remote workstations
**As of 9/30/03
Source: ChromaVision

An estimated 30% of cell-imaging services are performed for Medicare beneficiaries, but many managed care companies are likely to follow the government's new reimbursement policy as well. A ChromaVision spokesman says the company is now working to renegotiate its fees with all its customers. "We're hoping to find a medium ground," he says.

Of course, lower customer fees will put a big financial strain on both ChromaVision and Applied Imaging. In the nine months ended September 30, ChromaVision reported a net loss of $6.5 million versus a net loss of $7.2 million in the same period a year earlier; revenue was up 30% to $8.1 million. Over the same period, Applied Imaging, which makes the Ariol cell-imaging system, reported a net loss of $1.4 million versus a net loss of $213,000; revenue fell 4% to $15.1 million.

Medicare To Cover Immunoassay-Based FOBTs At $18.09 Per Test

The Centers for Medicare & Medicaid Services (CMS) has established a new CPT code (HCPCS code G0328) for immunoassay-based fecal occult blood tests (FOBTs) for colorectal screening and set the reimbursement level at $18.09. CMS's announcement that it would cover immunoassay-based FOBTs had raised hopes among the three vendors with FDA-cleared tests (*see DTTR, December 2003, p. 1*). But the subsequent release of the $18.09 reimbursement level has been a disappointment.

In fact, Robert Bruce, vice president of reimbursement at Enterix (Falmouth, ME), says that his company will close its U.S. operations and focus on other markets like

Australia and the United Kingdom unless CMS reconsiders its reimbursement level. It costs Enterix $25.50 to produce, distribute, market, and perform lab testing for its InSure test, assuming the company makes 750,000 kits per year, according to Craig Sands, chief executive at Enterix.

"We had hoped for a $28 Medicare reimbursement rate, and we weren't trying to pad it," says Bruce. He believes that CMS made a number of flawed assumptions when considering the cost effectiveness of immunoassay-based FOBTs. The primary error was that they compared immunoassay-based FOBTs to Beckman Coulter guaiac-based Hemmoccult II product, which has a low sensitivity.

CMS should have used Beckman's Hemoccult Sensa product for its cost-effectiveness studies because Sensa has a 50% market share and is gaining, according to Bruce. He notes that the Sensa product has a higher sensitivity than Hemoccult II and therefore leads to a greater number of expensive colonoscopies used to rule out colorectal cancer when FOBTs are positive.

Bruce says that Enterix has sent a strong letter of appeal to CMS, asking the agency to reconsider its reimbursement decision.

An executive at Beckman Coulter tells *DTTR* that his company, which had suggested a reimbursement level of $21 to $22 for immunoassay-based FOBTs, is now trying to figure out whether it is economically viable for Beckman to bring its FlexSure OBT test back into the market at the $18.09 reimbursement level.

Diagnocure Signs License Deal With Gen-Probe

Diagnocure Inc. (Toronto) has signed a licensing and collaboration agreement with Gen-Probe (San Diego) under which they will develop, and Gen-Probe will market, a diagnostic urine test for prostate cancer using Diagnocure's genetic marker, PCA3.

Clinical studies have shown that the PCA3 gene is overexpressed only in malignant prostate tissue. Diagnocure has developed a first-generation test for PCA3 called uPM3 that is offered in the United States on an ASR basis. The test is currently being performed by Bostwick Laboratories (Richmond, VA) on the Biomerieux EZQ platform. Bostwick charges clients approximately $300 to $400 per test (*see DTTR, November 2003, pp. 1-3*).

Pierre Desy, chief executive of Diagnocure, says that Gen-Probe is aiming to have an FDA-cleared, second-generation version of the test on the market within the next two to three years. This version will use Gen-Probe's Aptima technology and run on the company's Tigris system.

Under terms of the agreement, Gen-Probe will pay Diagnocure an upfront fee of $3 million and future fees and contract development payments of up to $7.5 million over the next three years. Gen-Probe gets exclusive worldwide rights to diagnostic products resulting from the deal, and will pay Diagnocure royalties of 8% on end-user net sales up to $50 million and 16% of end-user sales above $50 million.

Flextronics To Pay Beckman $23 Million

Flextronics (Los Angeles and Singapore) has agreed to pay Beckman Coulter (Fullerton, CA) $23 million to settle a breach-of-contract case that had resulted in a jury award of $934 million against the electronics manufacturer (*see DTTR, November 2003, p. 9*). The settlement includes about $18 million in punitive damages, $2 million for breach of contract, and $3 million for attorneys' fees and costs, according to attorney Daniel Callahan, who represented Beckman.

Nymox To Seek FDA Clearance Of Alzheimer Urine Test

Nymox Pharmaceutical Corp. (Maywood, NJ) plans to file a premarket approval application with the FDA for the company's Alzheimer urine test (AlzheimAlert) before year-end 2003, according to Michael Munzar, M.D., medical director. Nymox has performed homebrew versions of the test at its CLIA-certified lab in New Jersey since 1997. But physician adoption of the test, which has a list price of $295, has been slow. Munzar says an FDA-cleared kit version of AlzheimAlert could generate increased usage.

An estimated 4 million people in the United States have Alzheimer's disease, and there are 400,000 to 500,000 new cases every year, according to Munzar. He says that most doctors today rely on a combination of patient histories, MRIs, PET scans, and cerebral spinal fluid tests to diagnose the disease.

The AlzheimAlert test measures the level of a brain protein called neural thread protein (NTP) known to be elevated in the urine of patients with Alzheimer's disease. In company-funded trials for AlzheimAlert, involving over 500 clinical samples, the test has shown a sensitivity of over 80% for patients with verified Alzheimer's disease and specificity of over 89%.

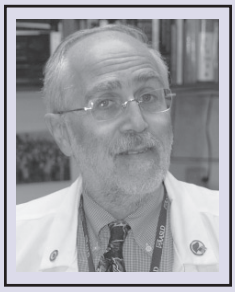
Nymox, which is also trying to develop new drugs to treat Alzheimer's, reported a net loss of $2.9 million in the nine months ended Sept. 30, 2003 versus a net loss of $2.5 million in the same period a year earlier; revenue fell to $167,266 from $306,104. Since beginning operations in 1995, Nymox has accumulated net losses of $30 million.

Mayo To Use Third Wave's Invader Technology

Mayo Medical Laboratories (Rochester, MN) says it has begun using the Invader genetic testing platform made by Third Wave Technologies (Madison, WI) to test for Factor V Leiden and Factor II mutations and a MTHFR mutation. These mutations are associated with increased risk of deep-vein blood clotting, or thrombosis, and heart disease. Mayo had previously used Roche's LightCycler platform for this testing.

Separately, Third Wave notes that its Invader platform is not a microarray-based system as erroneously reported in the December 2003 issue of this publication. Stephen Day, Ph.D., director of medical affairs at Third Wave, says Invader is a biochemical reaction performed in a liquid phase. It is not classified as a microarray because it is not performed at a microscopic level and because its use involves no immobilization of any reagents or substances onto a solid phase, according to Day.

Outlook For Lab Industry In 2004: Perspectives From 10 CEOs



Stephen Geller, M.D.

Stephen Geller, M.D., chairman of pathology at **Cedars-Sinai Medical Center** (Los Angeles), says reagent prices at his lab are rising by roughly 3% to 5%, with largest increases for immunoassays, molecular diagnostics, and transfusion medicine testing reagents. Meanwhile, routine chemistry reagent pricing continues to fall and microbiology is flat, according to Geller.

What do Geller and his staff desire most from reagent vendors? "Vendors should not exaggerate what their products can do," he advises. He notes that the past 12 months have been particularly troublesome in terms of reagent recalls and back orders. He believes this has a lot to do with the trend toward shifting more reagent manufacturing to cheaper labor markets outside the country. "The quality and consistency of products just doesn't seem to be as high as when they're made here," he observes.

Cedars-Sinai operates one of the largest hospital-based labs in California, employing 401 FTEs and performing 4.2 million billable tests per year, including 37% from outreach.

Cedars-Sinai uses a number of reference labs, including ARUP, Quest, Mayo, and Specialty Labs. Initiatives for the New Year include bringing genetic tests for cystic fibrosis and Fragile X syndrome in-house. Cedars-Sinai also plans to step up its outreach marketing efforts in the areas of hematology, molecular diagnostics, and oncology, according to Geller.

New initiatives for 2004 include the introduction of portable test systems (made by Nova Biomedical) into the pediatric intensive care units, says Geller. He says Cedars-Sinai is also in the final stages of installing an upgraded pneumatic tube system with the aim of continuing to do most stat testing at the hospital's central lab.

He says that since Quest acquired Unilab (February 2003) he has noticed a boost in the level of competition for physician office business from both Quest and Westcliff Medical Laboratories (Newport Beach), a mid-sized independent lab. Over the long term, however, Geller believes the doctor-to-doctor relationships, integration of inpatient and outpatient testing data, and 24-hour service that hospital-based labs provide will allow them to gain market share, if they can offer competitive prices.

Nate Headley

Nate Headley, chief executive of **Spectrum Laboratory Network** (Greensboro, NC), would like to see one of the big IVD manufacturers start marketing routine reagents that could be used across any vendors' instrument platform. "Generic reagents would simplify our operations dramatically and every lab would wind up buying from the vendor that offered them," he believes.

Spectrum is a for-profit independent lab with 740 employees. It is owned by Moses Cone Health System, High Point Regional Health System, and Novant Health System. It manages six inpatient labs plus a freestanding core lab in Greensboro. Headley says Spectrum grew its net revenue to a total of approximately $80 million last year from $65 million in 2002. Spectrum's core lab grew

by about 30% to $65 million, while inpatient testing, which is performed by Spectrum at cost, was flat at $20 million.

Headley says growth in 2003 was fueled by continued market share gains in North Carolina plus expansion into South Carolina. Spectrum also added 58 new tests to its menu last year.

Spectrum also invested $4 million to introduce an Internet-based order-entry and results-reporting system made by Atlas Development Corp. (Woodland Hills, CA). Headley says that 238 clients (representing 50% of Spectrum's volume) are now using the system to input their own accessions. Despite some initial glitches, he says ease of use, including touch-screen ordering, and the minimal amount of time needed to learn to use the system have sped physician office adoption.

Initiatives for 2004 include a major expansion into Tennessee and some minor expansion into northern Georgia, although there are no immediate plans for Atlanta, according to Headley.

Jim Fantus

Jim Fantus, president of **S.E.D. Medical Laboratories** (Albuquerque, NM), believes IVD vendors need to continue to focus on automation to help labs contend with the shrinking pool of medical technologists. They should also improve their processes so they don't have back orders when the FDA rejects a specific lot of reagents, according to Fantus. He says pricing for most reagents is moving up in line with inflation (*i.e.*, 2%-3% per year). However, he notes that S.E.D. is buying out most of its reagent rental contracts and purchasing analyzers outright, thus reducing supply costs.

S.E.D., which has 500 employees, 3.5 million billable tests, and approximately $45 million of collected revenue per year, is a for-profit independent lab owned by Ardent Health Services (Nashville, TN). S.E.D. acts as the reference lab for five hospitals owned by Ardent in New Mexico, including Lovelace Hospital and Albuquerque Regional Medical Center. S.E.D. also serves as the reference lab for other Ardent hospitals and other customers in 15 states.

Fantus says S.E.D.'s top priorities include expanding its test menu. Among the tests added last year were c-peptide, CA-15, homocysteine, BNP, highly sensitive CRP, tramadol, and fentanyl. Planned additions in 2004 include DNA-based HPV testing, HIV and HCV viral load, West Nile Virus, trileptal, and ketamine. Other initiatives include a potential geographic expansion into nearby states.

S.E.D. introduced an Internet-based results reporting system from CareEvolve (Elmwood Park, NJ) last year. Fantus says that only a handful of physician offices are up on the system at this time, but there is a long list of them waiting to be activated. Those that are up on the system are very pleased with it, he adds.

Joseph Holup, Ph.D., chief operating officer at **Clinical Laboratory Partners** (CLP—Newington, CT), says his lab grew its net revenue by more than 10% last year to approximately $35 million. Growth was fueled by the addition of several contracts, including Yale Health Plan, which covers 12,000 members, effective Oct. 1, 2003.

CLP, which has 400 employees and performs nearly 2 million billable tests per

year, is a for-profit independent lab owned by Hartford Hospital and Mid State Medical Center.

Holup believes that small and mid-sized labs will gain market share over time because "they understand the peculiarities of the local markets they serve." The advantage the two big commercial labs have, of course, is their ability to secure national managed care contracts, he adds.

Holup says reagent prices at CLP are rising only at a 1% to 2% annual rate. The bigger concern has been the disruption caused by reagent recalls at several of the larger IVD companies in the past year, he notes.

Initiatives for the New Year include bringing more tests in-house, particularly molecular tests for infectious disease, and expansion of CLP's service area, says Holup.

Gary Assarian, D.O., president and medical director of **Hospital Consolidated Laboratories** (HCL—Southfield, MI), says the best thing IVD manufacturers could do for their lab customers is improve instrument reliability and reduce recalls and back orders for reagents. "Over the past five years, the vendors have focused on making bigger boxes, but there's been little improvement in instrument reliability," says Assarian. "It's too expensive to have backups for consolidated chemistry-immunoassay platforms, so what does a lab do if there's a breakdown?" he asks.

HCL is an independent lab owned by Providence Hospital, Garden City Hospital, and Crittenton Hospital. The HCL core lab has 255 employees that perform approximately 2 million billable tests per year, of which 15% is reference work for the three hospitals and the remainder is from outreach; billable test volume systemwide is 5.3 million.

Assarian says competing with the big commercial labs is like trench warfare—even small gains are hard to come by. Over the long run, he believes that hospital labs will need to gain access to exclusive managed care contracts, now held by Quest and LabCorp, in order to grow their market share.

HCL introduced an Internet-based lab system from Labtest.com (Midland Park, NJ) last year. Physician response for the test-result reporting component has been good, while adoption of the order-entry component has not been as strong, according to Assarian.

Alan Kaye, president of *PathNet Esoteric Lab Institute* (Van Nuys, CA), says his top priority is expanding PathNet's test menu. PathNet, an independent for-profit lab with 85 employees, has traditionally been focused on women's health—more specifically, Pap smears and testing for sexually transmitted diseases. The company, which grew to $11 million in net revenue last year from $8 million in 2002, will also be increasing its sales staff, adds Kaye.

PathNet performs roughly 300,000 Pap tests per year, making it one of the largest cytology labs in the nation. The company currently uses Cytyc products for thin-layer testing, although the low prices offered by TriPath are tempting, says Kaye. He says PathNet will expand its menu this year to include hormone-based assays, cancer diagnostics, and possibly cystic fibrosis genetic analysis.

Kaye warns that he is seeing increased pressure from managed care companies in California to lower lab fees. He also notes that California's Medicaid program, Medi-Cal, lowered its reimbursement for all lab tests to 80% of the lowest Medicare maximum allowable rate effective Oct. 1, 2003.

Richard Borge, lab director at **Methodist Medical Center** (Peoria, IL), says reagent prices are increasing at about the same pace as the consumer price index (CPI), or about 3%. On his wish list from IVD vendors is all-inclusive pricing (*i.e.*, reagents, calibrators, disposable, control material, etc.) per reportable test result. This would make it easier for labs to calculate their budgets, according to Borge.

The lab at Methodist has a total of 130 employees (or 100 FTEs) and performs 1.7 million reportable test results (or 900,000 billable tests) per year. About 42% of test volume is from outreach.

Methodist's biggest competitors are Quest and LabCorp. Borge says that while the big commercial labs typically price their tests about 10% to 15% less, hospital labs have the advantage in terms of turnaround time and client service.

Methodist currently employs one dedicated salesperson for outreach and a client representative for existing accounts. Borge says Methodist is seeking to expand its outreach business and may lower prices a bit to achieve this goal in the coming year.

The fastest-growing costs at Methodist are blood products. Borge says that in the past, the American Red Cross has typically offered a "take it or leave it" attitude when pushing through its annual price hikes. But he says that ARC has recently shown more flexibility, and Methodist is now providing blood draws for ARC donors in exchange for better pricing.

Ken Geromini, executive director of **Life Laboratories** (Springfield, MA), is seeing minimal price increases for routine reagents. He believes the big IVD manufacturers should continue to wrap consulting-type services around their instrument and reagent sales to help labs improve their productivity and efficiency.

Life Laboratories is a for-profit independent lab owned by the Sisters of Providence Health System. Life has 255 employees (or 200 FTEs) that perform 2.5 million reportable test results per year, with $12 million in collected revenue and about 3% annual growth.

Geromini says the biggest challenge that hospital outreach programs face is raising their service levels to match those of independent labs and Quest and LabCorp. "Hospital labs are used to dealing with a captive audience, but a doctor's office won't switch labs unless they can get equal or superior service," he notes.

Initiatives for Life Laboratories in the coming year include bringing more tests in-house, including homocysteine, infectious disease tests, and parathyroid hormone. Geromini says Life, which currently covers western Massachusetts, is considering expansion to the north. He has considered offering Internet-based

test reporting services, but says only a handful of doctors have expressed an interest in it.

Michael Blanchette, administrator at **Clinical Laboratory of the Black Hills** (CLBH—Rapid City, SD), says purchasing groups have helped his lab keep reagent prices in check. In addition, Blanchette says that since most of Abbott's immunoassays were removed from the market a few years ago, his lab has avoided large, all-encompassing contracts with IVD vendors. Finally, he notes that aggressive pricing offers from TriPath have helped keep the lid on supply costs from CLBH's primary thin-layer vendor, Cytyc.

CLBH is a pathologist-owned independent lab that provides anatomic pathology services to Rapid City Regional Hospital. The lab has 70 employees and generates about $9 million per year in collected revenue.

LabCorp and Quest have a presence in South Dakota, which they each serve from main labs in Denver. Blanchette says the two big commercial labs are emphasizing Internet connectivity as a selling point to physician offices. As a result, he says CLBH plans to introduce an Internet-based results reporting system within the next 12 months.

The fastest-growing costs at CLBH include employee salaries and benefits, and send-out testing expenses. To stem employee costs, Blanchette says CLBH is relying more on lab technicians and phlebotomists to help with less technical work. Bringing more tests in-house is the strategy for lowering the trend in send-out costs. Recently added tests include C-reactive protein and homocysteine, with plans to add PSA (total and free) plus several tumor markers.

Over the long term, Blanchette believes consolidation of hospitals will lead to larger health systems that will have the ability to direct lab work from affiliated physician offices and outpatient centers to hospital labs. The role of the big commercial labs will increasingly be narrowed to non-time-sensitive reference testing, he adds.

Ellen Wright, lab manager for **PAPP Clinic Laboratory** (Newnan, GA), says her lab, which has 18 employees (or 11 FTEs) that perform about 250,000 tests per year, is preparing for a potential expansion of its services to other physician offices in the Atlanta area. The lab primarily serves the PAPP Clinic physician group, which includes 47 physicians and 6 clinics, and also provides testing services to the local home health care market. Test volumes at PAPP are currently rising by 1% to 2% per year, according to Wright.

PAPP recently installed its first laboratory information system (made by CyberLab) and plans to introduce an Internet-based reporting system. Wright says PAPP is also working to expand its test menu and will soon add tests for C-reactive protein and rheumatoid factor.

She says reagent prices have been fairly stable at PAPP. She attributes this to her frequent discussions with other labs to find out what they are paying and a willingness to walk away from vendors that won't budge on pricing. "You've got to do your homework and be willing to horse trade," adds Wright.

For interviews with another 10 lab Execs, including Quest's Ken Freeman, North Shore LIJ's Robert Stallone, and Clinical Pathology Labs' David Schultz, check out the January 2004 issue of DTTR's *sister publication,* Laboratory Industry Report. *For a free sample, send your name and mailing address to* labreporter @aol.com.

Immunicon Seeks Up To $86 Million From IPO

Many questions remain to be answered about Immunicon, including how much its tests will cost, who will reimburse labs for the test, and how on earth Wall Street will value a firm that has produced 20 years of losses and is now introducing its first product.

Immunicon Corp. (Huntington Valley, PA), which has developed a cell-based diagnostic system for detecting tumor cells in blood, has filed with the Securities and Exchange Commission for an initial public offering to raise up to $86.25 million. UBS Investment Bank, SG Cowen, Legg Mason, and Adams Harkness are managing the offering.

Funds raised from the IPO will be used to help Immunicon commercialize its cell-analysis technology, which is used to count and analyze tumor cells in the blood, known as circulating tumor cells (CTCs). A multicenter clinical trial of 177 metastatic breast cancer patients sponsored by Immunicon showed that the number of CTCs in blood samples drawn from patients at various time points predicted disease progression and survival.

The company has licensed its technology to Veridex LLC (owned by Johnson & Johnson). Veridex submitted a 510K application to the FDA in May 2003 for the use of the CellSearch Epithelial Cell Kit. CellSearch utilizes Immunicon's technology and will be used for the management of metastatic breast cancer. Immunicon expects Veridex to begin marketing CellSearch for research use only (RUO) in the first quarter of 2004 and then as an FDA-cleared kit in the second half of 2004. Under the distribution agreement, Veridex will pay Immunicon approximately 30% of net sales of CellSearch reagents and test kits. J&J owns an 11% stake in Immunicon.

Edward Erickson, 56, has served as the chairman of Immunicon since April 1998 and chief executive since March 1999. Erickson's previous experience includes CEO positions at both DepoTech Corp., a pharmaceutical company, and Cholestech, which makes point-of-care test systems for cholesterol screening. In 2002, Immunicon paid Erickson a salary of $239,912, bonus of $30,000 plus 350,000 stock options. He also owns 422,178 shares of the company, or 2% of the total outstanding.

Immunicon was formed in 1983 and has accumulated net losses totaling $58.7 million. In the nine months ended Sept. 30, 2003, the company lost $12.8 million on revenue of $2.1 million.

Whatever Happened To Careside?

Careside Inc. exists no more. After burning through $71 million of shareholders' money and loans over the course of six years, the company filed for Chapter 11 bankruptcy in October 2002 (*see DTTR, November 2002, p. 4*) and a few months later went Chapter 7. With a $600,000 loan, Palm Finance Corp. (Santa Monica, CA) had been Careside's biggest secured creditor and wound up seizing the company's assets. Palm Finance has shifted these assets into a shell company called Careside Medical LLC, which is now seeking investor funds to restart the company or a potential buyer. What went wrong at Careside? Steven Markoff, president of Palm Finance, tells *DTTR*, "The company suffered from an embarrassment of riches. Investors poured money into Careside, and the management went out of control spending it....The sad part is that the few customers that bought the Careside analyzer actually liked it."

Influenza Scare Lifts Quidel Stock Up 20%

***Roche** non-voting equity shares, which trade on the Zurich stock exchange, are up 23% to 118.25 Swiss francs so far this year. Shares of **Bayer**, which trade on the German stock exchanges, are up 8% to 22.12 euros.*

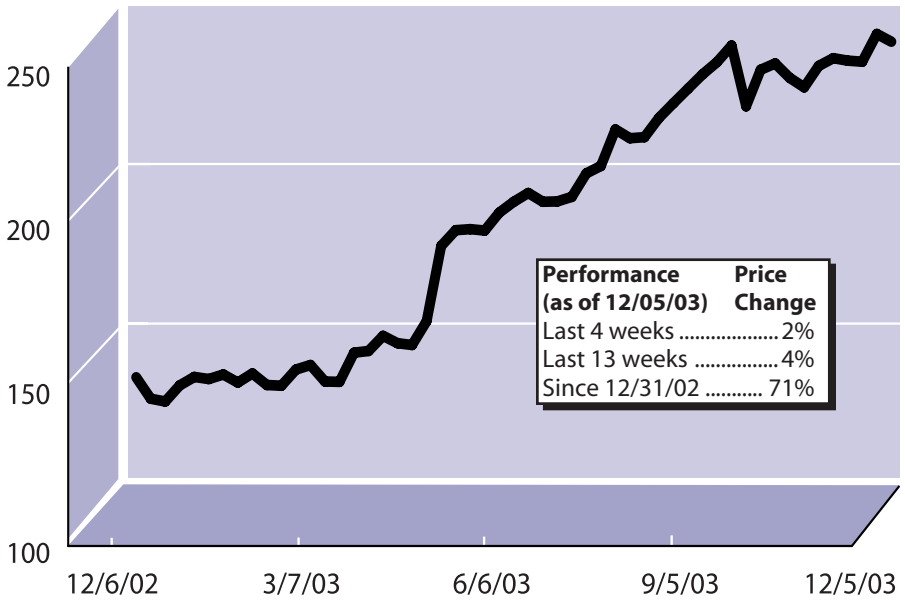
The 20 stocks in the G-2 Diagnostic Stock Index were up 2% in the four weeks ended Dec. 5, 2003, with 12 stocks up in price, one unchanged, and seven down. Year to date, the G-2 Index is up 71%, while the S&P 500 Index is up 21% and the Nasdaq is up 45%.

Shares of **Quidel Corp.** (San Diego) jumped 20% to $9.26 per share for a market cap of $270 million. The company, which makes a rapid point-of-care test for influenza called QuickVue, has been lifted by news that this flu season is shaping up to be the worst in a long time. Experts at the Centers for Disease Control and Prevention say the last time there was a flu strain mutation similar to the one sickening thousands of Americans this year was in 1998-99 when nearly 65,000 people died.

In the United States, flu season typically runs from November through April, with the largest number of cases seen between late December and early March. According to the CDC, influenza infections cause more than 114,000 hospitalizations and 36,000 deaths (more than 90% are over age 65) in the typical year.

Quidel's QuickVue influenza test is a lateral flow immunodiagnostic test that detects the influenza A and B virus in about 10 minutes from a nasal swab sample. The test has an average selling price of about $16 and is carried by most U.S. distributors, including PSS, Cardinal Health, Henry Shein, McKesson, and Fisher HealthCare. In 2002, Quidel sold 1.6 million QuickVue influenza tests in the United States and estimated sales for 2003 are 2.8 million tests, according to a company spokeswoman.

G-2 Diagnostic Stock Index



Source: The G-2 Diagnostic Stock Index is tabulated weekly by *DTTR* from the average percentage change in the stock price of 20 IVD companies.

% Price Change, 4 weeks ended 12/5/03

UP	PRICE	% CHG
Abbott Labs	$44.96	4%
Becton Dickinson	40.00	10%
Biosite	26.12	1%
Cytyc	13.16	1%
Dade Behring	33.53	7%
Diagnostic Products	44.74	7%
Digene	38.50	7%
Gen-Probe	31.32	4%
Igen	59.65	3%
Immucor*	23.78	14%
Meridian	11.47	13%
Quidel	9.26	20%
UNCHANGED		
Johnson & Johnson	49.22	0%
DOWN		
Beckman Coulter	50.60	-1%
Bio Rad	51.01	-6%
Cholestech	7.00	-8%
Inverness Medical	21.12	-14%
i-STAT	11.98	-4%
TheraSense	17.64	-5%
Ventana	35.00	-14%

*Shares of Immucor recently split 3-for-2

G-2 Insider

Ortho-Clinical Diagnostics (OCD—Raritan, NJ), a unit of Johnson & Johnson, has announced plans to restructure its operations. OCD, which has approximately 3,750 employees worldwide, is cutting 500 positions, including 230 positions in the United States. The targeted cuts are focused on streamlining the company's marketing, customer service, and technical support areas, according Mary Richardson, spokeswoman for OCD.

Other changes include the retirement of Gerard Vaillant, company group chairman for worldwide diagnostics. His replacement is Roy Davis, who has been with J&J since 1984, most recently as group president in charge of Advanced Diagnostic Systems, Therakos, and Virco. In addition, Cliff Holland, who has been with J&J since 1978, has been named president of OCD. Most recently Holland was president of J&J's Ethicon unit. Holland replaces Catherine Burzik, who resigned from OCD earlier this year to become an executive vice president at Applied Biosystems (Foster City, CA).

Separately, J&J reports that revenue (unadjusted for currency changes) at OCD climbed 7% to $868 million in the nine months ended Sept. 30, 2003, including a 3% gain in U.S. sales to $441 million and an 11% increase in international sales to $427 million.

Late Breaking News: **Abbott Labs** has agreed to acquire **i-Stat** (East Windsor, NJ) for $15.35 per share, or approximately $392 million, in cash. Abbott has marketed i-Stat's hand-held blood analyzers since 1998, but i-Stat had made plans to resume direct distribution of its products effective Jan. 1, 2004. Full details in the next issue of *DTTR*.

Company References

Beckman Coulter 714-871-4848
Careside Medical 310-587-1470
Cedars-Sinai Medical Ctr 310-855-5000
ChromaVision 949-443-3355
Clinical Laboratory of the Black Hills 605-343-2267
Clinical Laboratory Partners 800-286-9800
Diagnocure 418-527-6100
Enterix 207-781-4990
Hospital Consolidated Laboratories 800-365-0106
Immunicon 215-830-0777
Life Laboratories 413-748-9500
Methodist Medical Center 305-672-5522
Nymox 514-332-3222
Ortho-Clinical Diagnostics 908-218-1300
PAPP Clinic 770-253-6616
PathNet, 818-780-6300
Quidel Corp. 858-552-1100
SED Medical Laboratories 800-999-5227
Spectrum Laboratory Network 336-664-6100
Third Wave 608-273-8933

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