Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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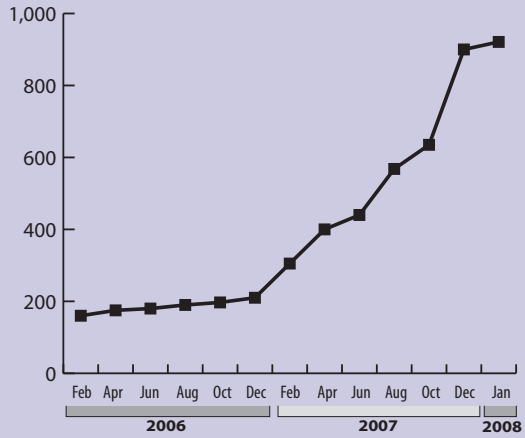
Retail Clinics Expected to Top 1,500 by Year End

With slogans such as "No appointment. No waiting. No hassle." and "Check in. Check up. Check out," retail health clinics are a small but rapidly growing presence in today's healthcare industry, and they are increasingly touted as a convenient, cost-effective destination for diagnostic testing. Last year, the number of retail clinics in the United States more than quadrupled, from just over 200 to 921, and the California HealthCare Foundation (CHCF) estimates that there will be more than 1,500 retail clinics by the end of 2008.

For more on retail clinics, see *Inside the Diagnostics Industry*, p. 5.

Retail Clinics in the U.S.



Source: Verispan

FDA Approves Dako's TOP2A Gene Test for Breast Cancer Patients

On January 14, the U.S. Food and Drug Administration (FDA) announced its approval of the first test to detect or confirm changes in the topoisomerase 2 alpha (TOP2A) gene in cancer patients. The pharmacogenomic test can help physicians to assess the risk of breast cancer tumor recurrence and long-term survival for patients with relatively high-risk breast cancer. It is expected to be used as an adjunct to HER2 testing. Known as TOP2A FISH pharmDx, the test is manufactured by Dako (Glostrup, Denmark), the cancer diagnostics company that was purchased last year by private equity fund EQT (Stockholm, Sweden).

TOP2A FISH pharmDx uses fluorescent in situ hybridization (FISH) to detect or confirm abnormalities in TOP2A, a 170kDa gene that codes for a nuclear enzyme involved in DNA replication. Localized to chromosome 17, TOP2A is the target of cancer drugs known as anthracyclines, and a variety of mutations in this gene have been associated with the development of drug resistance. *Continued on p. 2*

▲ **FDA Approves Dako's TOP2A Gene Test,** *from page 1*

Amplifications or deletions in the TOP2A gene in breast cancer cells can indicate an increased likelihood of tumor recurrence or decreased likelihood of long-term survival.

Anthracycline-based chemotherapy (e.g., doxorubicin, epirubicin) has serious acute and long-term side effects, such as cardiotoxicity and leukemia. Information about a patient's TOP2A genetic profile can help physicians to optimize use of anthracycline therapy. Dako notes that this is an active area of research "with promising initial results that require confirmation and extension in the context of currently available chemotherapeutic options."

According to the FDA, the TOP2A FISH pharmDx test is suitable for breast cancer patients who are premenopausal or for whom tumor characteristics, such as tumor size or lymph node involvement, suggest a higher likelihood of tumor recurrence or decreased survival.

In studies of high-risk breast cancer tumors excised from 767 patients in 21 centers in Denmark, Dako confirmed that the test was useful in estimating time to local or distant recurrence and overall survival in women who received certain chemotherapy regimens.

Dako, which receives 48% of revenues from European sales and 34% from sales in North America, previously received CE-mark status for TOP2A FISH pharmDx. The company's pharmacogdiagnostic portfolio also includes tests for detection of HER2 gene amplification, HER2 protein overexpression, EGFR protein, and estrogen and progesterone receptor proteins.

Genomic Health to Partner With Pfizer on Kidney Cancer Test

Affecting approximately 25,000 people in the United States each year, clear-cell renal carcinoma is the most common type of kidney cancer in adults.

Genomic Health (Redwood City, CA) will partner with pharmaceutical powerhouse Pfizer (New York, NY) to develop a prognostic test for non-metastatic renal cell carcinoma (RCC). The kidney cancer test will be developed using the molecular technology and clinical strategy of Genomic Health's flagship product, OncotypeDX, a prognostic test for early-stage breast cancer patients.

The new test is intended to estimate the risk of recurrence following surgery for patients with Stage I-III renal carcinoma of the clear cell type that has not metastasized. "Many early-stage renal carcinoma patients experience a recurrence of their cancer, yet there is no accurate way to identify the most aggressive cancers in advance," said Chu Chang, vice president of business development at Genomic Health. "This collaboration further expands our efforts to develop genomic tests for a variety of cancers that allow physicians and patients to individualize treatment decisions."

Pfizer could ultimately use the test in concert with axitinib, its investigational cancer drug (a selective inhibitor of VEGF receptors) that has been shown in a Phase II clinical study to have anti-tumor activity in advanced RCC patients who were resistant to multi-kinase therapy.

FDA Okays First Rapid Blood Test for Drug-Resistant Staph

The Food & Drug Administration (FDA) has cleared for marketing the first rapid blood test for the drug-resistant staph bacterium known as MRSA (methicillin-resistant *Staphylococcus aureus*), which can cause potentially deadly infections such as blood stream infections, surgical site infections, or pneumonia.

The test, the BD GeneOhm StaphSR Assay, is manufactured by BD Diagnostics, a subsidiary of BD (Franklin Lakes, NJ). The test uses molecular methods to identify whether a blood sample contains genetic material from the MRSA bacterium or the more common, less dangerous staph bacterium that can still be treated with methicillin. The BD assay provides results within two hours, directly from positive blood cultures.

Methicillin is an antibiotic that has been used successfully to treat infections from the *Staphylococcus aureus* bacterium. Over the years, the staph bacterium mutated and spawned MRSA, a strain that is resistant to methicillin and which has a higher rate of being fatal.

"The BD GeneOhm test is good news for the public health community," said Daniel G. Schultz, M.D., director of FDA's Center for Devices & Radiological Health, in a January 2 announcement of test approval. "Rather than waiting more than two days for test results, healthcare personnel will be able to identify the source of a staph infection in only two hours, allowing for more effective diagnosis and treatment."

List price for the BD GeneOhm StaphSR assay is $39.50 per test, a BD representative tells *DTTR*. The test will first be made available in boxes of 48 tests.

The test should be used only in patients suspected of a staph infection, the FDA cautioned. It should not be used to monitor treatment for staph infections nor should results be used as the sole basis for diagnosis. Also, the FDA noted, the test will not rule out other complicating conditions or infections.

BD has submitted applications to the FDA for the BD GeneOhm StaphSR assay to add nasal swab and wound claims. Meanwhile, the company is developing rapid tests that will identify the vanA and vanB genes, which are associated with vancomycin-resistant enterococci and the toxin gene associated with *Clostridium difficile*.

Genizon BioSciences Raises $31 Million

Genomic research and analysis company Genizon BioSciences (Montreal, Quebec) has closed on a Series E financing round of CAD$31 million (USD$30.8 million, at current exchange rates), the company announced January 7. The investment was led by biotechnology-focused venture capital fund BTF (Haarlem, Netherlands). Since 1999, Genizon has raised over $130 million in funding. Along the way, it has inked licensing deals with the likes of Genentech and Pfizer.

Formerly known as Galileo Genomics, Genizon has used its unique platform to create "GeneMaps" of such conditions as schizophrenia, endometriosis, and Crohn's disease. Among the company's current projects is mapping rheumatoid arthritis and Alzheimer's disease. In addition to mapping interacting genes and biomarkers, Genizon offers high throughput SNP genotyping, genetic analysis, gene expression, and pharmacogenomics services.

Now the company plans to zero in on the genomic underpinnings of metabolic syndrome, a condition that is believed to affect approximately 50 million Americans. Part of the new investment will be used to finance additional genomic studies of the four major diseases associated with the condition: obesity, type II diabetes, dyslipidemia, and hypertension. The new funds will also be used to enhance and commercialize discoveries already generated from the previous studies.

CMS to Delay Anti-Markup Provisions for Diagnostic Tests

The Centers for Medicare & Medicaid Services (CMS) has delayed until Jan. 1, 2009, the applicability of the anti-markup provisions under the Stark self-referral rules with respect to certain services performed in certain locations.

The delay applies to the professional component of purchased diagnostic tests payable under the physician fee schedule. It does not apply to the technical component of these tests. It also does not apply to any anatomic pathology diagnostic testing services furnished in space that (1) is utilized by a physician group practice as a "centralized building" for purposes of complying with the Stark rules and (2) does not qualify as a "same building" under the rules.

In a final notice published January 3, CMS said it was concerned that the definition of "office of the billing physician or other supplier" may not be entirely clear and could have unintended consequences. The agency says that during the next 12 months, it plans to issue clarifying guidance as to what constitutes the "office of the billing physician or other supplier," propose additional rule making, or both.

FDA OIVD to Hold 510(k) Workshop in April

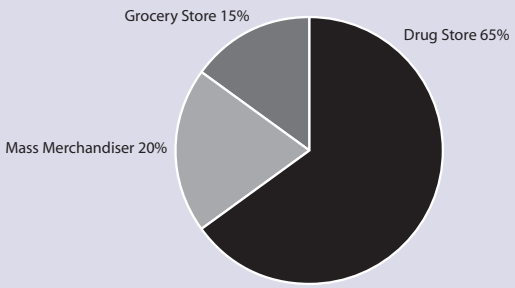
The Office of In Vitro Diagnostic Devices (OIVD) at the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) and the Association of Medical Diagnostics Manufacturers (AMDM) will co-sponsor the OIVD's Annual 510(k) Workshop on April 22-23, 2008, at the Marriott Bethesda North Hotel and Conference Center (Bethesda, MD). Designed to foster communication between the professional, manufacturing, and regulatory communities, the workshop will feature sessions led by FDA personnel who review 510(k) submissions. This year's workshop will also include a half-day hands-on training on Turbo 510(k), the electronic 510(k) submission program. Further information and registration information is available at *www.amdm.org*.

A Closer Look at Retail Health Clinics

Today there are approximately 920 retail health clinics operating in 36 states. While this market performs or affects only a tiny fraction of the nation's diagnostic testing, it is a rapidly growing segment that has test manufacturers and providers taking a closer look as payers, retail giants, and consumers continue to embrace the "convenient care" model that is their key selling point. The California HealthCare Foundation predicts that by 2012, there will be 6,000 retail clinics in the United States.

Most retail clinics offer a limited menu of services and are staffed by nurse practitioners who are supported by an off-site physician. According to MinuteClinic (Minneapolis, MN), the biggest player in the retail health clinic market, its visit times average 15 minutes, and services (most of them reimbursed by insurance plans, according to the company) are priced between $30 and $110. MinuteClinics are open seven days a week.

Stores Hosting Retail Clinics, by Type



Source: California HealthCare Foundation (2007)

The majority (65%) of retail clinics are located inside drug stores. In 2006, CVS/Caremark acquired MinuteClinic for an estimated $170 million, and last year, Walgreens acquired Take Care Clinics (Conshohocken, PA). Both chains have announced plans to add hundreds of locations nationwide.

Mass merchandisers host 20% of retail clinics. Wal-Mart, for example, contracts with QuickHealth (San Francisco, CA), MedPoint Express (South Bend, IN), and CheckUps (Tampa, FL), while Target has its own brand of in-store clinic. Grocery chains, which now host 15% of retail clinics, are also recognizing their potential, with Publix, Kroger, and Wegmans all announcing plans to add more clinics to their stores.

Top 10 Retail Clinics in the United States

Company	*# of Locations**	*State(s)*
MinuteClinics	390	Nationwide (CVS)
Take Care Clinics	136	Nationwide (Walgreens)
The Little Clinic	40	FL, GA, IN, KY, OH
Redi Clinic	33	Nationwide (Wal-Mart, H-E-B)
Corner Care Clinic	25	CT, IL, IN, PA, SC
Target Clinics	24	MD, MN
Checkups	23	AL, FL, LA, MS
Aurora Quickcare	22	WI
Healthstop (SmartCare)	22	CO, PA
Curaquick	12	IA, NE, SD

*As of December 31, 2007

Source: Verispan

But who are the consumers for retail clinics? And are they turning to these facilities for diagnostic tests? Recent studies have found that the retail clinic consumers are no longer dominated by the uninsured. Preventative screening tests, however, remain among the lower-priority reasons for consumers to use retail clinics. In a recent Harris survey of retail clinic consumers, 44% reported that they went for vaccinations, 33% for treatment of a common medical condition such as an ear infection, and 19% for preventative screening tests.

New Delhi Lab Sees Future in Outsourced Testing

Since it was infused with over $7 million in venture capital funding in 2005, New Delhi-based Dr. Lal PathLabs has been pushing an ambitious growth plan, a primary component of which is to acquire a United States lab to begin outsourcing diagnostic testing services for uninsured Americans to India.

"We are willing to give United States customers testing services at 30% lower costs, and we will match industry standards in terms of turnaround times," said Sachin Shetty, president of Lal PathLabs' United States partner, Ssurepath (Ashburn, VA). "We understand that the entire United States lab testing market is not able to be outsourced, but we are trying to figure out a way to reach the 47 million or more uninsured Americans who have no way of getting diagnostic testing done. We haven't exactly figured it out yet, but our goal is to be able to serve these people."

With 27 labs, 500 patient service centers, and a menu of 1,650 tests and panels, 59-year-old Lal Pathlabs is well-positioned to take advantage of the price advantage of testing in India. In the United States, for example, a HIV antibody test would be priced at approximately $38, while in India, Lal Pathlabs charges $8 for such a test.

The proposed delivery model calls for two central Ssurepath facilities in the United States—a central lab and a consolidating facility. Critical and local samples would be picked up by Ssurepath couriers, while nonlocal samples would be picked up by UPS or DHL. Those samples that were from Medicare patients would be transported to the Ssurepath Lab for processing, while non-Medicare samples would be shipped to the consolidation facility and then on to a Lal Pathlabs facility in India for processing. For reporting, anatomic pathology slides would be shipped to customers, while clinical pathology reports would be electronically transmitted over a secure server.

Currently, Ssurepath and Lal Pathlabs are not yet outsourcing any samples from the United States to India. Ssurepath is currently an anatomic pathology lab that receives about 1,500 samples a month that are processed at local labs. They are, however, doing outsourcing trials for some of their clients as they look for an appropriate CLIA-certified acquisition candidate in the United States.

"We are not sending anything to India as of yet, and the reason for this is billing regulations, which mandate that we acquire a lab here in the United States," said Shetty. "Between Lal Pathlabs and Ssurepath, we are trying to acquire a lab in the United States, so we can be reimbursed by Medicare and other insurance providers. Other options are also now on the table. While we are looking for our own lab, we are also open to partnering with other labs."

Test Pricing: United States vs. India

Test	*U.S.**	*India***	*% India/ U.S.****
Antinuclear antibody test	$25	$12	68
Vitamin B12	$33	$19	73
Parathyroid hormone + calcium	$77	$29	44
Hepatitis C antibody	$51	$26	61
Hemoglobin A1c	$24	$7	50
C-reactive protein	$24	$7	50
HIV viral load	$171	$93	57

*Prices of leading U.S. laboratory; **Prices of Lal Pathlabs; ***Calculated after factoring in $5 per sample logistics costs from U.S. to India

Source: Lal Pathlabs

New Gene Variants Linked With Heart Disease Risk Factors

Using genome-wide association studies, researchers have associated levels of cholesterol and triglycerides to 18 genetic variants, according to a paper appearing in the January 13 advance online issue of *Nature Genetics*. The findings have the potential to help predict a patient's genetic risk of heart disease.

Researchers scanned the genomes of over 27,000 people to locate single nucleotide polymorphisms (SNPs) associated with blood lipid levels. They found 18 SNPs associated with levels of LDL cholesterol, HDL cholesterol, or triglycerides. Twelve of the SNPs were already known to influence lipid levels, while the other six SNPs are entirely new: two are associated with LDL cholesterol, one with HDL cholesterol, and five with triglycerides. While the biological effects of many of the SNPs are not clear, they may influence lipid levels by regulating the expression of nearby genes. Future research will probe the DNA surrounding the 18 genomic regions identified in the *Nature Genetics* study.

This work could lead to a test that would enable physicians to identify patients at high risk for heart disease at an earlier stage and then use cholesterol-lowering drugs to prevent future damage to blood vessels.

Industry Groups Respond to SACGHS Report on Genetic Testing

Late last year, the Department of Health and Human Services (HHS) Secretary's Advisory Committee on Genetics, Health & Society (SACGHS) issued new recommendations for oversight of genetic testing (see January *DTTR*, p. 2), recommending that the Centers for Medicare & Medicaid Services (CMS) beef up CLIA quality and enforcement safeguards, and the Food and Drug Administration follow a more broadly consultative course in regulating lab-developed tests (LDTs). Both the American Clinical Laboratory Association (ACLA) and the College of American Pathologists (CAP) reacted favorably to the recommendations, but with some caveats. Both groups contend that CMS should be the lead federal agency to oversee genetic testing services, and both contend the FDA should take a "go slow" consultative approach to regulating genetic test products.

In a statement to SACGHS, CAP said genetic testing practiced in the United States "is safe and effective, even for tests that are not FDA-cleared or approved, thanks in large part to CLIA regulations combined with medical oversight of every clinical lab by a physician…Not all LDTs are genetic tests and different rules for genetic LDTs would be inappropriate, given the high-quality testing already in place." Requiring FDA approval for every LDT would be harmful to patients, CAP said, because it would stifle innovation, limit access to beneficial tests, and slow test development.

Reliance on CLIA standards does not mean the FDA has no role to play, ACLA said in its statement to SACGHS: "It should have a clearly defined consultative role in providing comment to the CLIA program on clinical validity and promotional claims for certain high-risk genetic LDTs."

In defining genetic tests, CAP believes that this group of tests is not unlike many

of the other lab tests that have been successfully introduced into medical practice and warns against an overly broad definition of genetic tests that could "capture many non-genetic tests that have not raised public concern—for example, serology assays that detect and measure proteins encoded by genes undergoing rearrangement and somatic mutation." ACLA also warns against an overly broad regulatory definition.

Public comments on the SACGHS report and the revised recommendations will be discussed at the committee's next meeting (Feb. 12-13, 2008), and the recommendations finalized. SACGHS says it is on track to deliver a final report to the HHS Secretary well before its July 2008 deadline.

Genzyme Licenses Protein Markers for Lung Cancer Test

Genzyme (Cambridge, MA) has obtained exclusive worldwide diagnostic rights to the Tampa, Florida-based H. Lee Moffitt Cancer Center and Research Institute's discovery that the expression levels of two proteins correlates with the response of patients with non-small cell lung cancer (NSCLC) to certain cancer drugs. Genzyme plans to develop and market a diagnostic test that can be used to measure the expression levels of these proteins—known as RRM1 and ERCC1—in NSCLC patients. Such a test could then inform the selection of a first-line treatment for these patients.

Moffitt researchers led by Gerold Bepler, M.D., found that levels of RRM1 and ERCC1 protein levels could be correlated with NSCLC patient response to platinum drugs and gemcitabine, which are commonly used therapies for NSCLC. "Lung cancer is responsible for more cancer deaths in women than breast cancer and more deaths in men than prostate cancer," said Bepler, program leader of Moffitt's thoracic oncology program. "We hope this test will advance our fight against this disease and improve treatment options for patients."

While specific financial terms of the license agreement were not disclosed, Genzyme has agreed to pay Moffitt when various milestones are reached and provide Moffitt with running royalties on the sales of licensed services and products.

FDA Clears Real-Time PCR Assay for Respiratory Viruses

Prodesse (Milwaukee, WI) has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its ProFlu+ assay for use with the Roche Diagnostics MagNA Pure LC System and the Cepheid SmartCycler II. The assay uses real-time polymerase chain reaction (PCR) to simultaneously detect and differentiate among influenza A virus, influenza B virus, and respiratory syncytial virus (RSV). ProFlu+ is an upgraded version of Prodesse's ProFlu-1, a research use only (RUO) assay that will be discontinued this summer.

ProFlu+ uses real-time PCR to amplify and quantify a specific sequence in a DNA sample. Because the method requires minimal hands-on time, it has a low risk of amplicon contamination.

"We are convinced that we made the right choice choosing real-time PCR as our

core technology platform," said Tom Shannon, CEO of Prodesse. "Laboratorians are telling us that the 'big box' multiplex systems are cumbersome and more appropriate for epidemiological, not clinical, applications."

Results from the ProFlu+ Assay are available in approximately three hours. Pricing for the assay varies based on volume, Prodesse Chief Marketing Officer Andy Shrago tells *DTTR*, but list price is $52.50 per reaction.

In a multi-site clinical study of 826 patient samples that compared the ProFlu+ assay to traditional culture methods, the assay demonstrated an overall clinical sensitivity and specificity of 98% and 83%, respectively. The decreased specificity was the result of the ProFlu+ assay detecting more positive samples than culture. Further testing by genetic sequencing determined that 87 of the 103 samples that were positive by ProFlu+ but negative by culture were likely true positives.

ProFlu+ is the first in a series of real-time respiratory assays for which Prodesse is seeking FDA clearance. Prodesse's Pro hMPV+ assay for detection of human metapneumovirus is currently in clinical trials. The company will also soon begin clinical trials on two other tests: ProParaflu+, a multiplex assay for differentiating parainfluenza viruses, and ProGastro Cd to detect *Clostridium difficile*. ProFlu+, Pro hMPV+, ProParaflu+, and ProGastro Cd will use a common internal control so that a single nucleic acid extraction can be used with multiple assays.

Caris Diagnostics to Acquire Molecular Profiling Institute

Subspecialty-focused pathology services provider Caris Diagnostics (Irving, TX) has agreed to acquire Molecular Profiling Institute Inc. (MPI; Phoenix), a CLIA-certified molecular diagnostics company and reference laboratory focused on developing and commercializing novel molecular diagnostic tests based on genomic and proteomic profiling. Financial terms of the acquisition agreement were not disclosed.

A specialty reference laboratory with approximately 50 employees, MPI provides prognostic testing services and resources for genomic and proteomic profiling to help guide physicians in the treatment of cancer and other diseases. Among the specialty reference laboratory's proprietary products are Target Now (a late-stage cancer panel to guide targeted therapy selection), Mammostrat (an early-stage breast cancer prognostic test), and the CardioEvaluatR program (a cardiovascular disease management panel).

The MPI acquisition is in line with Caris Diagnostics's plans to advance the commercialization of personalized medicine, said company chairman David D. Halbert. "MPI significantly expands our ability to help ensure that through the right diagnosis, patients get the right treatment, in the right dosage, at the right time," he explained. "In addition, we are eager to help bolster MPI's capacity to partner with leading pharmaceutical companies and academic institutions in facilitating targeted drug development."

Formed in 1996, Caris Diagnostics operates three laboratories: in Irving, Texas; Phoenix, Arizona; and Newton, Massachusetts. Although both Caris and MPI have Phoenix laboratories, the two companies plan to maintain both facilities.

FDA Licenses Olympus Blood-Typing Tests, Clears Instrument System

The U.S. Food and Drug Administration (FDA) licensed 14 new tests for determining a person's blood type. Marketed by Olympus (Center Valley, PA) and manufactured by Diagast (Loos Cedex, France), the tests are known as the Olympus PK System Blood Group and Phenotyping Reagents. They are approved for use on the Olympus PK7200 Automated Microplate System.

Packaged in ready-to-use vials, the tests use monoclonal antibodies to test for the A, B, O, and Rh factors, as well as for other factors that signify a rarer blood type. The color-coded reagents require no handling, manipulation, or dilution—only that users transfer them to the appropriate locations on the instrument.

"These 14 new tests will provide blood establishments and transfusion services with additional choices to help assure safe, well-matched transfusions," said Jesse L. Goodman, M.D., M.P.H., director of FDA's Center for Biologics Evaluation and Research. "The tests offer a broader diversity of reliable blood-typing tests and will help protect against product shortages."

The FDA also recently cleared the Olympus PK7300 automated microplate system for use in the United States. Designed for blood donor centers, the system offers clot detection, reagent monitoring, and primary reagent vial sampling. According to Olympus, the company's systems are used to test more than 90% of the North American blood supply.

Quest Focuses on Cancer Testing and Point-of-Care Diagnostics

Last year, Quest Diagnostics (Madison, NJ) acquired HemoCue (Angelholm, Sweden) for $420 million and AmeriPath (Palm Beach Gardens, FL) for $2 billion. These purchases are now fueling the lab testing leader's focus on growing its point-of-care (POC) testing and cancer diagnostic businesses, company chairman and CEO Surya Mohapatra, Ph.D., at the JPMorgan Healthcare Conference on January 8 in San Francisco.

Mohapatra compared the AmeriPath acquisition to Quest's purchase of the SmithKline Beecham Clinical Laboratories (SBCL). "Just like when Quest acquired SBCL in 1999, [which] established a rise in the quality of clinical pathology, the acquisition of AmeriPath, and its joining with Quest to become the world's largest cancer diagnostic company will be the game change for our industry," he explained.

In addition to the POC testing and cancer diagnostics growth, Mohapatra said that the expansion of Quest's operations to India, along with increasing clinical trial testing and leveraging healthcare IT assets will further enrich Quest's portfolio. "These . . . things open up multimillions of dollars in opportunity for us in the next five to 10 years," he said. The company is expected to grow at higher than the industry growth rate by expanding operating income by 20% in the next five years, with 10% of the revenue coming from the international market, he added.

IVD Stocks Fall 2%; BD Climbs on MRSA Test Clearance

The 19 stocks in the G-2 Diagnostic Stock Index fell an average of 2% in the five weeks ended January 11, with 9 stocks up in price, eight down, and two unchanged. In the same five-week period, the Nasdaq fell 10% and the S&P 500 dropped 7%.

News that the U.S. Food & Drug Administration (FDA) approved its GeneOhm system rapid staph infection test (see p. 2) sent shares in **Becton Dickinson** (Franklin Lakes, NJ) to an all-time high. Shares in the medical equipment and diagnostic test company climbed 11% to $91.21 for a market capitalization of $22.52 billion. The company has scheduled its first-quarter earnings call for January 24.

Also getting a boost from regulatory news was **Luminex** (Austin, TX), which gained 3% to $16.60 per share for a market capitalization of $643 million. In early January, the maker of the xMAP system received 510(k) clearance from the FDA for its xTAG respiratory viral panel (RVP), which detects 12 viruses and viral subtypes that together are responsible for more than 85% of respiratory viral infections. Formerly known as Tag-It and acquired by Luminex with its 2007 purchase of TmBioscience, the xTAG technology uses multiplex polymerase chain reaction (PCR) on bead-based microarrays.

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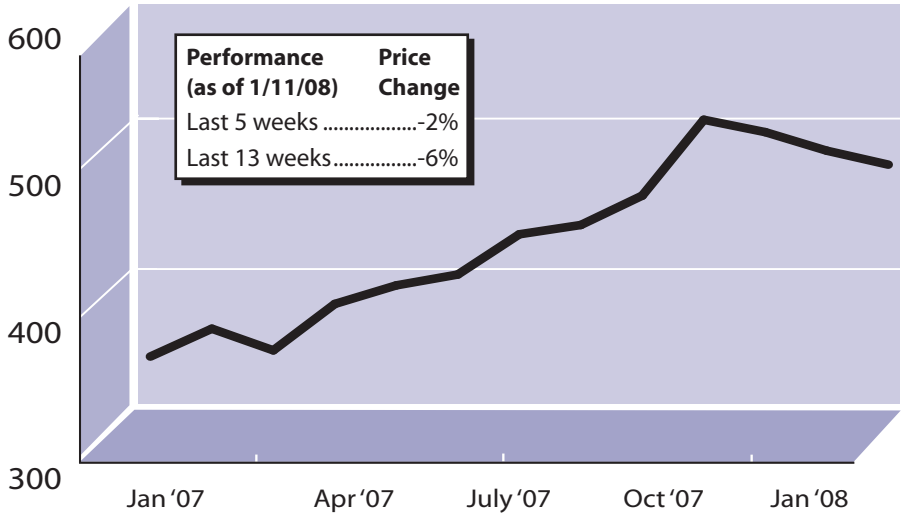
Ventana Medical Systems (Tucson, AZ) slipped 1% to $87.90 per share for a market capitalization of $2.98 billion. Meanwhile, Roche continues its attempt to purchase the tissue-based cancer diagnostics company. On January 16, Roche re-extended its $2.63 billion tender offer until March 14. The hostile bid had been set to expire January 17. Ventana CEO Christopher Gleeson reiterated his stance that his company is worth more than Roche's offer of $75 per share and continues to recommend that stockholders not tender any of their shares to Roche at what he calls "this inadequate price."

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 19 IVD companies.

UP	Price	% Chg
Abbott Labs	$60.50	4%
Abaxis	36.51	5
Affymetrix	22.50	5
Beckman Coulter	72.90	3
Becton Dickinson	91.21	11
Inverness Medical	60.02	2
Luminex	16.60	3
Meridian	34.28	8
Nanosphere	14.08	13
UNCHANGED		
Johnson & Johnson	$67.88	0%
Third Wave	9.12	0
Down		
Bio-Rad	$97.89	-6%
Clinical Data	20.70	-16
Gen-Probe	62.70	-2
Immucor	31.12	-4
Nanogen	0.33	-45
OraSure	8.82	-2
Quidel	16.49	-12
Ventana	87.90	-1

G-2 Insider

Proteomic approach identifies liver cancer better than traditional biomarkers . . . A new form of proteomic profiling using technology known as SELDI-TOF MS (surface enhanced laser desorption/ionization time of flight mass spectrometry) is more accurate than traditional biomarkers in distinguishing liver cancer patients from those with hepatitis C liver cirrhosis, a study in the January 15 issue of *Clinical Cancer Research* finds.

The recent increase in liver cancer incidence is due largely to the spread of hepatitis C, a virus that can lead to liver cirrhosis, a potentially fatal condition that can greatly increase a person's chances of developing liver cancer. "Right now, there is no reliable means of detecting liver cancer at an early stage, when surgical treatment is an option," says the paper's co-senior author Nezam Afdhal, M.D., director of the Liver Center at Beth Israel Deaconess Medical Center (BIDMC; Boston).

Serum protein biomarkers of cancer, such as alpha fetoprotein (AFP), have been viewed as the best hope for early detection, but AFP often fails to detect early tumors and lacks specificity. Using SELDI-TOF MS, the investigators identified an 11-protein signature that accurately discriminated between the cirrhosis and cancer patients in a group of 92 patients. The resulting diagnostic value (74% sensitivity and 88% specificity) compared favorably with that of AFP (73% sensitivity and 71% specificity), as well as with two other biomarkers in clinical development for liver cancer, AFP-L3 and PIVKA-IL.

"Most strikingly, in patients with small tumors (less than 2 cm), where AFP identified only three, and AFP-L3 and PIVKA-II only one each, the 11-protein signature correctly identified seven of eight patients at this early stage of disease," notes co-senior author Towia Libermann, Ph.D., director of the Genomics Center at BIDMC.

Company References

ACLA 202-637-9466
BD 201-847-6800
CAP 800-323-4040
Caris Diagnostics 800-979-8292
CMS 877-267-2323
Dako 45-44-85-95-00
FDA OIVD 240-276-0450
Genizon BioSciences 514-270-3991
Genomic Health 866-662-6897
Genzyme 617 252 7500
Inverness 781-647-3900
Luminex 512-219-8020
Olympus 800-645-8160
Prodesse 262-446-0700
Quest Diagnostics 201-393-5000
Roche 41-61-688-1111
SACGHS 301-496-9838
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