Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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Vol. VIII, No. 12/August 2008

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WASHINGTON G-2 REPORTS

Established 1979

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California Cracks Down on DTC Genetic Testing

The California Department of Public Health (CDPH) is cracking down on companies offering direct-to-consumer (DTC) genetic testing, including such Silicon Valley "personal genomics" startups as 23andMe (Mountain View, Calif.), which promises individuals "deeper insights into personal ancestry, genealogy, and inherited traits" in return for $999 and a saliva sample. In June, CDPH sent notices to 13 laboratories to cease and desist performing genetic testing for California residents until the laboratories meet the requirements specified in state laws.

According to California state law, any laboratory offering genetic tests to California residents must be licensed as a clinical laboratory in California. Additionally, tests must be ordered by a licensed physician and validated. Tests for paternity and genealogy are not subject to these laws. Among the companies CDPH notified were 23andMe, Navigenics, deCODE Genetics, Knome, and DNATraits. Since last November, the New York State Department of Health has sent letters to 31 companies notifying them that they need to be licensed by the state in order to solicit DNA samples from New York residents. For more on this story, see *Inside the Diagnostics Industry*, p. 5.

Monogram Launches Breast Cancer Assay

Molecular diagnostics company Monogram Biosciences (South San Francisco, Calif.) is launching its first oncology product. Beginning July 15, the company will offer HERmark, a test that quantifies HER2 protein expression in patients with breast cancer to determine whether each can benefit from the drug Herceptin (trastuzumab). The HERmark test will be marketed to physicians nationwide and performed at Monogram's College of American Pathologists (CAP)-certified clinical laboratory. List price for the test is $3,350, and turnaround time is seven days.

Speaking at the Collins Stewart Growth Conference in New York City on July 8, Monogram CEO Bill Young described oncology as "a real inflection point for the company, something that we've been working toward since we acquired Aclara Biosciences." That December 2004 deal gave Monogram the proprietary VeraTag (formerly known as eTag) technology used in the HERmark test.

HERmark measures both total HER2 protein and levels of HER2 homodimers, a significant improvement over the semi-quantitative methods currently used to determine HER2 status as an indicator of HER2 protein overexpression or HER2 gene amplification. HERmark test results are *Continued on p. 2*

▲ **Breast Cancer Assay,** *from page 1*
presented in a report that indicates a specific quantitative measurement of the levels of HER2 total protein and HER2 homodimer, together with a comparison of the patient's level of HER2 total protein relative to reference ranges. The report classifies the patient's tumor as HERmark "positive," "negative," or "equivocal."

Distinct from fluorescent in situ hybridization (FISH), polymerase chain reaction, microarrays, and immunohistochemistry (IHC), VeraTag is a proximity-based method that uses multi-labeled antibodies to detect and quantify protein-protein complexes of the HER family of tyrosine kinases in formalin-fixed, paraffin-embedded tissue specimens.

Monogram has correlated the HERmark assay with IHC, FISH, and chromogenic in situ hybridization results obtained in central laboratories in more than 1,000 patients. "We see a high degree of concordance between the best central lab tests and HERmark," said Michael Bates, M.D., vice president of clinical research at Monogram. "Importantly, HERmark identifies patients with high HER2 levels but who are HER2-negative by other assays, as well as some patients with low HER2 levels but who are judged positive by conventional assays. Comparisons with local lab results by IHC or FISH suggest significantly larger numbers of discordant results."

To commercialize the test, Monogram is hiring oncology-focused sales and medical affairs staff. The company will focus on introducing HERmark to medical oncologists in both key centers of excellence and large community hospitals throughout the United States.

Invitrogen, Applied Biosystems to Combine in $6.7B Deal

Invitrogen (Carlsbad, Calif.) and Applera (Norwalk, Conn., and Foster City, Calif.) have agreed to combine in a deal that would create a biotechnology reagents and systems giant with approximately $3.5 billion in combined sales and 9,700 employees. Under the terms of the agreement approved in June, Invitrogen will acquire all of the outstanding shares of Applera's Applied Biosystems Group (AB) in a cash and stock transaction valued at $6.7 billion. Following the close of the transaction, expected this fall, the combined organization will be called Applied Biosystems and will be headquartered in Carlsbad.

According to the merger agreement, Applera-Applied Biosystems shareholders will receive $38 for each share of Applera-Applied Biosystems stock they own in the form of Invitrogen common stock and cash. The expected split between cash and stock is 45 percent and 55 percent, respectively, with a per-share premium of 17 percent over AB's closing price on June 11, or 12 percent to the average closing price in the previous 30 trading days.

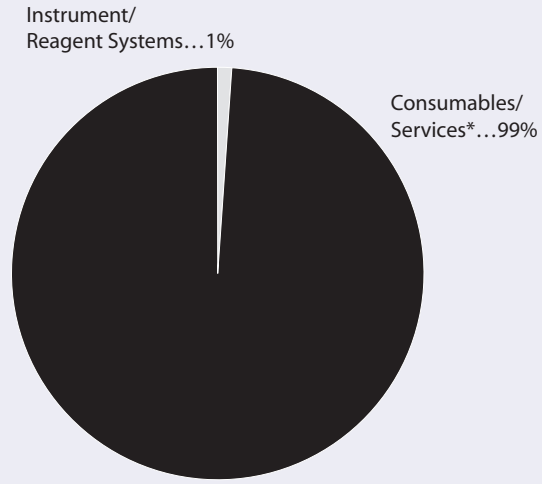
After the deal closes, the new company's board of directors will be composed of the nine current Invitrogen board members and three additional members from the current Applera board. Invitrogen's Gregory T. Lucier will be chairman and CEO of the combined company, and Mark P. Stevenson will become president and chief operating officer, a position he has held since December 2007 at AB.

With 4,700 employees, Invitrogen had revenues of $1.32 billion in fiscal 2007. The 21-year-old company provides consumables and services to pharmaceutical and

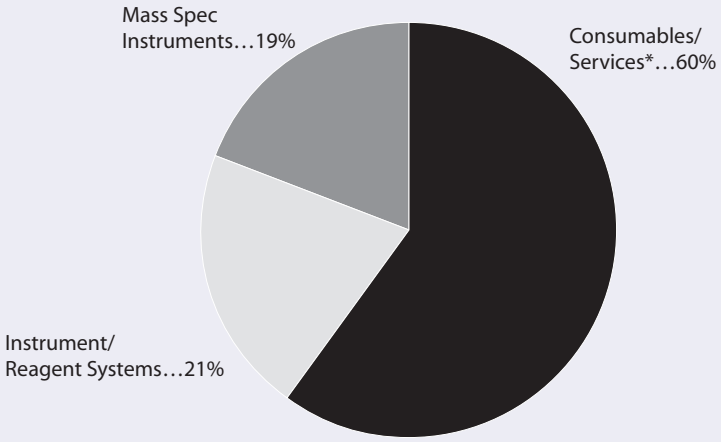
biotechnology companies, as well as academic and government research institutions. Its brands include Molecular Probes, Gibco, and Dynal Biotech. The company's clinical and diagnostic products include transplant diagnostics, anatomical pathology reagents, and immunoassays.

Founded in 1981, AB has approximately 5,000 employees and reported 2007 sales of $2.17 billion. The company is focused on the basic research, commercial research (pharmaceutical and biotechnology), and such testing markets as forensic human identification, paternity testing, and food testing. The company has an installed base of approximately 180,000 instrument systems in nearly 100 countries.

Invitrogen
2007 Revenue: $1.32 billion



Applied Biosystems
2007 Revenue: $2.17 billion



*Includes intellectual property royalties
Source: Invitrogen and Applied Biosystems

In a conference call with investors and analysts to discuss the planned transaction, Applera Chairman and CEO Tony L. White described the deal as a hybrid of two of the "strategic options" the company had been considering: restructuring and remaining independent and selling to another company.

In recent years, AB has worked to diversify by building its consumables business, a focus which led to the 2006 acquisition of RNA-focused company Ambion. "This strategy has been quite successful, to the point that AB's revenues from consumables now exceed revenue from instruments," said White, adding that a second growth strategy has been to increase the use of AB's molecular technology in such testing markets as forensics.

"With this acquisition, we are nearly doubling our consumables business as almost half of Applied Biosystems' revenues are consumable in nature," said Lucier, chairman and CEO of Invitrogen. The combined company will generate greater than 70 percent of its revenue from consumables and services and have an intellectual property portfolio of approximately 3,600 patents and exclusive licenses.

Within three years, the transaction is expected to generate approximately $125 million in cost savings and at least $50 million in additional annual operating income from materials, sourcing, and revenue synergies. The closure of the transaction is subject to regulatory approval, as well as approval of shareholders in both companies.

BD's *C. difficile* Molecular Test Gets CE Mark

BD Diagnostics, a segment of Becton, Dickinson, and Company (BD; San Diego, Calif.), has received the CE mark for its molecular test for the rapid diagnosis of *Clostridium difficile* infection. BD has submitted the assay to the U.S. Food and Drug Administration for clearance. List price is $49.50 per test.

The BD GeneOhm Cdiff molecular assay is CE marked under the European In Vitro Diagnostics Directive for the identification of toxigenic *C. difficile* directly from stool specimens. The qualitative test uses real-time polymerase chain reaction (PCR) to target the toxin B gene, which is found in toxigenic strains of the bacteria. Results of the test are available in less than two hours, a significant improvement over "gold standard" tissue culture methods, which require several days to yield results. The molecular assay also has higher sensitivity than the many available immunoenzymatic assays for rapidly detecting *C. difficile* toxins.

The test does not differentiate between active and prior *C. difficile* infection. However, it "is intended to be used with symptomatic patients," a BD representative tells *DTTR*. "If these patients are positive for the toxin B gene then it would be considered an active infection."

C. difficile bacteria are a primary cause of hospital-associated infections, which have in recent years reached epidemic proportions worldwide. In the United States, an estimated 500,000 people are hospitalized and more than 28,000 die from *C. difficile* infections each year, while in the United Kingdom, *C. difficile* infections have risen 40 percent in the last three years, infecting eight times as many patients as methicillin-resistant *Staphylococcus aureus* (MRSA) and killing twice as many.

J&J Acquires Swedish IVD Company

Johnson & Johnson's Nordic unit (Sollentuna, Sweden) has acquired Amic (Uppsala, Sweden), a developer of in vitro diagnostic (IVD) technology for use at the point of care, to bolster J&J-owned Ortho-Clinical Diagnostics. Johnson & Johnson expects to incur an estimated one-time after-tax charge of approximately $40 million during the second quarter of 2008 related to the deal. Other details of the transaction were not disclosed.

Amic's proprietary "Forecast" technology uses a chip-based micro-fluidic platform to enable fully quantitative, immunoassays in POC or near-patient settings. The company was founded in 1998 to commercialize a technology for mass production of microstructures in plastic but refocused its business on the IVD market in 2003.

Worldwide commercial president of Ortho-Clinical Diagnostics Mark Straley called the acquisition "a strategic opportunity to develop a point-of-care channel," adding that Ortho-Clinical is "committed to bringing novel assays and existing tests closer to the patient and delivering information to health care professionals when and where they need it."

DTC Genetic Testing Under Greater Scrutiny

The California Department of Public Health (CDPH) is following the lead of the New York State Department of Health in cracking down on companies that offer genetic tests directly to consumers (DTC). In June, CDPH sent notices to 13 companies (listed below) ordering them to cease and desist performing genetic testing for California residents until they meet state laws that 1) require that all clinical laboratories in California or receiving biological specimens originating in California for the purpose of performing a clinical laboratory test or examination possess a clinical laboratory license or registration; and 2) prohibit the offering of a clinical laboratory test directly to the consumer without a physician order, unless specifically exempt.

Signed by CDPH chief of laboratory field services Karen L. Nickel, Ph.D., the letters highlighted the relevant sections of California's Business and Professions Code and directed each company to submit a plan to the CDPH by late June that would demonstrate how the company "will prevent further violation of California state laboratory law." The CDPH is now reviewing company responses.

In the meantime, companies were notified that "Any advertising for genetic services, whether it be in written word or by Internet, must clearly state that this testing is prohibited for California residents." Additionally, each company was ordered not to take unsolicited requests for genetic tests from California residents.

Much of the testing solicited by the notified companies is in fact contracted to large, Clinical Laboratory Improvement Amendments (CLIA)-certified laboratories. For example, Navigenics (Redwood Shores, Calif.) contracts its testing to Affymetrix's clinical laboratory, which passed the State of California survey for CLIA certification in April of 2007. In a statement issued in late June, 23andMe (Mountain View, Calif.) noted that its testing is also "conducted in an independent CLIA-certified laboratory and we utilize the services of a California-licensed physician." Both Navigenics and 23andMe continue to accept samples from California residents.

Companies Notified by California Department of Health

- 23andMe
- CGC Genetics
- deCODE Genetics
- DNA Traits
- Gene Essence
- HairDX
- Knome
- Navigenics
- New Hope Medical
- Salugen
- Sciona
- Smart Genetics
- Suracell

Source: California Department of Public Health

The nascent industry of personal genomics has heightened concerns about regulation of genetic testing and privacy issues, even in the wake of President George W. Bush's May 21 signing of the Genetic Information Nondiscrimination Act (GINA). "First and foremost, we need to ensure that genetic tests are safe, reliable, and marketed in a clear and truthful manner," wrote Kathy Hudson, Ph.D., M.K. Holohan, and Francis Collins, M.D.,

Ph.D., in an editorial published in the *New England Journal of Medicine* on June 19. "There are important gaps in the oversight of genetic tests, and multiple advisory groups have called for regulatory reform to ensure the analytic and clinical validity of genetic tests."

Meanwhile, the Federal Trade Commission has begun investigating the advertising and marketing of genetic tests, and consumer-directed genetic testing is expected to be a priority of the Secretary's Advisory Committee on Genetics, Health, and Society in coming months.

FDA Sends ASR 'Reminder' Letters to IVD Manufacturers

In June, the United States Food & Drug Administration's (FDA) Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), Center for Device and Radiological Health, sent a letter to manufacturers who have listed analyte specific reagents (ASRs) with the FDA, reminding them to ensure that their Class II or Class III in vitro diagnostic devices that are currently inappropriately labeled and marketed as ASRs comply with the law by September 15 of this year.

Last September, the FDA published *Guidance for Industry and FDA Staff Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions*, a guidance document that sought to clarify the roles and responsibilities of ASR manufacturers. Describing ASRs as "building blocks of laboratory-developed tests," the document emphasized that, "when an ASR is marketed in combination with other products, with instructions for use, or with specific claims, FDA views the product as no longer being an ASR . . . and therefore not necessarily exempt from premarket notification." The guidance also clarified FDA's view of ASRs as intended to detect a single target.

'We believe that, in most cases, clearance or approval of products in their existing configurations is in the best interest of the public health.'

In the reminder letter, OIVD Director Steve Gutman, M.D., wrote, "Although modification of products inappropriately marketed as ASRs so that they are brought within the scope of the ASR definition is an option to reach compliance, we believe that, in most cases, clearance or approval of products in their existing configurations is in the best interest of the public health."

The letter also states that in addition to premarket submissions, FDA is willing to accept pre-Investigational Device Exemption (IDE) submissions before September 15. The FDA recommends that pre-IDE submissions include a clear plan for each device with a premarket timeline for submission and a detailed outline of the intended use and studies/data that are planned for the premarket submission(s).

The FDA says that it "intends to work interactively with manufacturers to reach agreement on a premarket submission plan." When agreement cannot be reached, or if manufacturers do not pursue the agreed upon plan, the FDA warns that it may take enforcement action with respect to the affected products.

Dako Partners With Bristol-Myers Squibb for Companion Diagnostics

Tissue-based cancer diagnostics company Dako (Glostrup, Denmark), which was purchased last year by Sweden-based private equity group EQT, has announced a collaboration with Bristol-Myers Squibb (New York, N.Y.). Dako will develop clinical diagnostics to identify cancer patients who may receive greater benefits from certain drugs being developed by the pharmaceutical giant.

"Dako's tests will be developed as companion products for specific Bristol-Myers Squibb investigational therapeutics," says Patrik Dahlén, CEO and president of Dako. "We believe it is important for pharmaceutical companies and diagnostic companies to combine their expertise into a strong collaborative approach to enable development of diagnostic tests for use with drug therapies."

The partnership will expand the use of Dako's pharmDx line of pharmacodiagnostic assays, which include fluorescent in situ hybridization (FISH)- and immunohistochemistry-based tests to assess expression of such cancer-associated protein targets as epidermal growth factor receptor (EGFR), HER2, and c-kit. In January, the United States Food and Drug Administration granted Dako approval to market its TOP2A FISH pharmDx assay, which is intended to be used as an adjunct in determining prognosis for high-risk breast-cancer patients.

In 2007, Dako entered into a collaboration agreement with Genentech, OSI Pharmaceuticals, and Roche to study its EGFR pharmDx assay for use as an aid in the assessment of patients with a diagnosis of non-small cell lung cancer who might benefit from treatment with Tarceva (erlotinib), a selective inhibitor of EGFR.

Bristol-Myers's current cancer drugs include Erbitux (cetuximab) for colorectal cancer, Ixempra (ixabepilone) for breast cancer, and Sprycel (dasatinib) for myeloid leukemia and acute lymphoblastic leukemia. On June 26, Bristol-Myers completed its $190 million acquisition of Kosan Biosciences (Hayward, Calif.), a pharmaceutical company focused on the clinical development of two new classes of anticancer agents: heat shock protein 90 inhibitors and epothilones.

Rosetta Genomics Buys Parkway Clinical Labs for $3m+

To amplify the marketing and development of its microRNA-based tests, Rosetta Genomics (Jersey City, N.J.) has acquired Parkway Clinical Laboratories (PCL; Bensalem, Pa.) in a deal potentially worth $3.1 million. PCL's revenues in 2008 are expected to be close to $3 million, putting the acquisition price at a 1.1x revenue multiple.

PCL operates a 5,000 square foot CLIA-certified lab and has 33 full-time employees. PCL's CEO, Raza Bokhari, M.D., will be joining Rosetta as chief development officer. Bokhari acquired PCL in April 2003 after selling Lakewood Pathology Associates (Lakewood, N.J.) to Water Street Healthcare Partners (Chicago), which has reportedly invested close to $50 million in the pathology practice.

Eight-year-old Rosetta currently has an agreement with two CLIA-certified labs, in New York, at Columbia University Medical Center's high-complexity molecular pathology laboratory and at the University of California Irvine School

of Medicine. Both labs are involved in developing and validating tests based on Rosetta's microRNA technology.

On June 25, Rosetta announced its first women's health-focused development initiative. The company has partnered with the Rabin Medical Center (Petah Tikva, Israel) to develop microRNA-based diagnostic and prognostic tests in the fields of oncology, gynecology, and obstetrics. Affiliated with the Sackler School of Medicine at Tel Aviv University, Rabin Medical Center consists of Beilinson and Golda-Hasharon Hospitals, which have a total of 1,300 beds and 4,500 staff members.

New Biomarker-Based Test Predicts Prostate Cancer Recurrence

According to research published in the June 15 issue of *Clinical Cancer Research*, the presence of seven biomarkers can predict with 86.6 percent reliability whether a patient who has had prostate cancer surgery will have a recurrence or spread of the disease. This is at least 15 percentage points higher than standard clinical measures currently in use, the researchers say.

Shahrokh F. Shariat, M.D., chief resident in urology at the University of Texas Southwestern Medical Center and lead author of the study, maintains that results of the test could aid clinicians in deciding whether to take a "watchful waiting" approach with prostate cancer patients or to pursue more aggressive therapy such as hormone therapy, chemotherapy, or radiation. Urologists currently use a risk predictor that includes variables like stage, Gleason score, and serum levels of prostate-specific antigen. "However, this method is only accurate about 70 percent of the time, which is not optimal," Shariat said.

The study enrolled 423 patients who were surgically treated for prostate cancer with either radical prostatectomy or bilateral lymphadenectomy. Using commonly available blood tests, they measured levels of seven biomarkers: transforming growth factor-β1, interleukin-6, interleukin-6 soluble receptor, vascular endothelial growth factor, vascular cell adhesion molecule-1, endoglin, and urokinase plasminogen activator.

Patients were followed for approximately four years, and researchers noted cancer recurrence in 17.7 percent of patients. Elevated levels of the seven biomarkers were associated with increased risk of relapse. For example, the presence of urokinase plasminogen inhibitor-1 increased risk by 37 percent, while the presence of vascular endothelial growth factor increased risk by 47 percent. The combination of all seven biomarker variables accurately predicted risk 86.6 percent of the time in this study.

"This is a large and unique improvement for patient care," said Shariat. "Neither preoperative MRI nor any of the clinical features we have used before even comes close to this level of accuracy."

Elevated Fetuin-A Levels Associated With Increased Diabetes Risk

Having a higher than normal level of fetuin-A, a protein produced in the liver and secreted into the blood stream, is associated with an increased risk of developing diabetes, according to a study published in the July 9 issue of the *Journal of the American Medical Association*.

Researchers at the University of California, San Diego and San Diego Veterans Affairs Healthcare System conducted a study to examine whether higher fetuin-A levels are associated with the occurrence of diabetes in older people. The study included 406 persons (age 70 years to 79 years) without diabetes at the start of the study, who had fetuin-A levels measured at baseline and had six years of follow-up. Diabetes developed in 135 participants.

Analysis indicated a graded increase in the incidence of diabetes with increased fetuin-A levels. The third of the group with the highest levels had more than twice the incidence rate compared with the lowest third. The association was independent of physical activity, inflammatory biomarkers, and other commonly available measures of insulin resistance and was irrespective of sex, race, and obesity status.

"Future studies should evaluate whether the results may generalize to middle-aged individuals in whom the [diabetes] incidence rate is highest," note the authors of the *JAMA* report. "If confirmed in future studies, fetuin-A may ultimately prove useful as a target for therapeutics, and its study may provide novel insights to glucose metabolism in humans."

Urinary Albumin Levels Can Predict Hypertension

Healthy individuals with higher levels of albumin excretion, even levels considered normal, are at increased risk of developing high blood pressure (hypertension), according to a study that will appear in the October 2008 issue of the *Journal of the American Society Nephrology* (*JASN*) and was published online in late June. The study suggests that to prevent cardiovascular disease, the definition of "normal" urinary albumin excretion should be reconsidered.

A variety of studies have shown that higher levels of urinary albumin excretion, even within the normal range, are associated with cardiovascular disease in individuals with diabetes or hypertension. However, because less research has been done in low-risk populations, it is unclear whether elevated levels of albumin in the urine might indicate that generally healthy individuals are at risk of developing cardiovascular disease, which claims more than 800,000 lives each year.

To clarify the issue, researchers at the Brigham and Women's Hospital (Boston, Mass.) looked at the new development of hypertension among 2,179 women without baseline hypertension or diabetes and with normal levels of urine albumin. The researchers discovered that higher levels of urinary albumin excretion, even within the range considered normal, increased an individual's risk of developing hypertension.

Among older women (median age of 65 years), those with the highest levels of albumin excretion were 76 percent more likely to develop hypertension than those with the lowest levels. For younger women (median age of 44 years), the risk was 35 percent higher. These elevated risks held true when factors such as body mass index, blood pressure, smoking, and family history of hypertension were taken into account.

The authors conclude that their results, in conjunction with the findings of other studies, suggest that "it is time to re-evaluate our current concept of 'normal' albumin excretion."

Boston Researchers Awarded Grant for Breast Cancer Biomarkers

Massachusetts General Hospital (MGH) and Northeastern University's Barnett Institute have received a three-year, $1.26 million grant from Susan G. Komen for the Cure (Dallas, Texas) to carry out novel breast cancer research. Researchers from both institutions will use the joint award to discover protein biomarkers that can predict which women with benign diagnoses will go on to develop breast cancer and which will remain cancer free.

As part of the research study, co-principal investigators Dennis C. Sgroi, M.D., of MGH and Barry L. Karger, Ph.D., of Northeastern will work to identify breast cancer-associated proteins (BCAPs) that may prove valuable disease biomarkers. Sgroi's research group will validate the candidate BCAPs in a cohort of benign breast cancer patients at MGH. Each BCAP will be evaluated individually, as well as in combination with other BCAPs.

"We anticipate that through this process we will identify a proteomic biomarker signature that is prognostic for increased breast cancer risk for these patients," said Sgroi, director of breast pathology at MGH, and associate professor of pathology at Harvard Medical School. "The development of such a biomarker signature will help clinicians better identify the subset of benign breast disease patients who likely benefit from aggressive breast cancer monitoring and therapeutic prevention strategies."

CMS Adds More Waived Tests to Lab Fee Schedule

Not waiting for the next annual update of the Medicare clinical lab fee schedule, the Centers for Medicare and Medicaid Services is adding 13 more waived tests to the schedule, effective July 1 with an implementation date of July 7. The tests are the latest approved by the Food and Drug Administration as waived under CLIA (the Clinical Laboratory Improvement Amendments).

Waived testing is the least-regulated CLIA category, requiring mainly that the user follow the manufacturer's instructions. In billing for these tests, the CPT codes must have the modifier QW to be recognized as waived.

CPT Code	*Descriptor*
80047QW	Basic metabolic panel (calcium, ionized)
80048QW	Basic metabolic panel (calcium, total)
80051QW	Electrolyte panel
80053QW	Comprehensive metabolic panel
82042QW	Albumin; urine or other source, quantitative, each specimen
82150QW	Amylase
82247QW	Bilirubin; total
82977QW	Glutamyltransferase, Gamma (GGT)
84075 QW	Phosphatase, alkaline
84157 QW	Protein, total, except by refractometry; other source
84520 QW	Urea nitrogen; quantitative
87808 QW	Infectious agent antigen detection by immunoassay with direct optical observation; *Trichomonas vaginalis*
87999 QW	Unlisted microbiology procedure

The number of waived tests grew from nine tests in 1993 to more than 1,600 test systems and 76 analytes in 2007, according to a recent report on the national status on laboratory medicine. The report was commissioned by the Centers for Disease Control and Prevention and released late last month (see *DTTR*, July 2008, p. 12).

IVD Stocks Fall 9%; Third Wave Rises on Takeover News

The 18 stocks in the G-2 Diagnostic Stock Index fell an average of 9 percent in the five weeks ended July 3, with 14 stocks down in price, two up, and two unchanged. The G-2 index is down 18 percent so far this year, while the Nasdaq is down 14 percent and the S&P 500 has fallen 13 percent.

While **OraSure** and **Clinical Data** plummeted 27 percent and 21 percent, respectively, deal news kept the share prices of a few IVD companies afloat in a tough market. **Third Wave Technologies** (Madison, Wis.) gained 7 percent in recent weeks, with a July 3 closing price of $11.19 per share and a market capitalization of $493 million. On June 9, women's health-focused Hologic announced that it had agreed to acquire Third Wave, known for its proprietary Invader test platform. The purchase price of $11.25 per share, or approximately $580 million, represented a premium of about 24 percent to Third Wave's average trading price over the last three months.

On June 25, Hologic announced that the Federal Trade Commission had cleared the deal, granting the company an early termination of its antitrust review. The transaction is expected to close in the third quarter.

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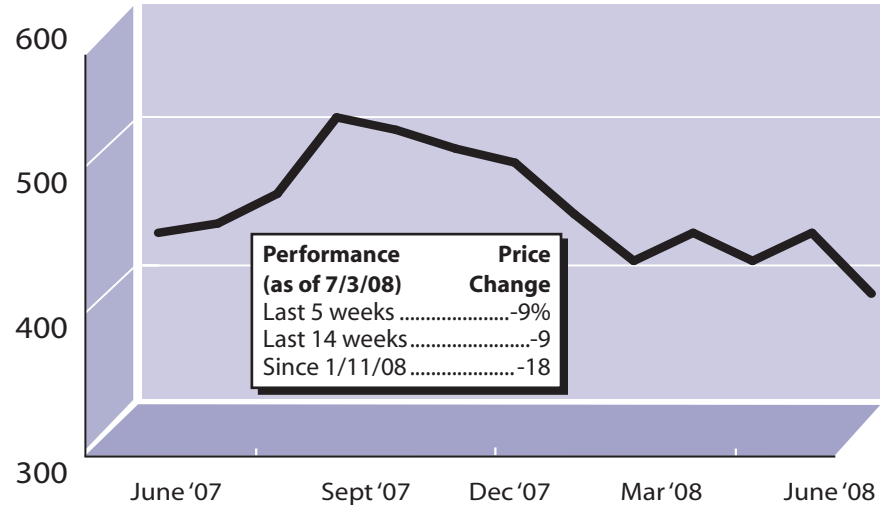
Meridian Bioscience (Cincinnati, Ohio) slipped 9 percent, ending the period with a share price of $27.54 and a market capitalization of $1.11 billion. On June 19, the company completed its $653,000 acquisition of technologies and products from Vybion, a biotechnology company. Meridian plans to use the infectious disease recombinant proteins and cardiac antigens in its infectious disease diagnostic tests, as well as for tests that monitor protein levels in patients with HIV, hepatitis C virus, herpes simplex virus, and cardiac disease. The products will be manufactured at Meridian Life Science, Meridian's wholly owned subsidiary in Memphis, Tennessee.

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 18 IVD companies.

UP	PRICE	% CHG
Nanogen	$0.39	5%
Third Wave	11.19	7
UNCHANGED		
Abbott Labs	54.75	0
Becton Dickinson	82.35	0
DOWN		
Affymetrix	9.82	-18
Abaxis	23.72	-21
Beckman Coulter	68.59	-2
Bio-Rad	80.90	-6
Clinical Data	13.65	-21
Gen-Probe	47.54	-9
Immucor	24.94	-7
Inverness Medical	32.15	-13
Johnson & Johnson	65.12	-1
Luminex	19.88	-9
Meridian	27.54	-9
Nanosphere	7.35	-26
OraSure	4.00	-27
Quidel	16.00	-7

G-2 Insider

Lab Institute 2008 to Tackle Changing of the Guard . . . Join Washington G-2 Reports for its 26th annual Lab Institute, September 17-19 at the Crystal Gateway Marriott in Arlington, Va. This year's program, "Changing of the Guard: Working With a New Administration, the New Millennial Generation, and a New Health Care System," examines fundamental realignments in politics, Medicare and health care reform policy, personalized medicine, and the molecular diagnostics market. At this year's Lab Institute, you will:

- ❑ Hear from the nation's foremost thought leaders on the future of health care policy and lab industry trends;
- ❑ Go inside the boardroom and hear what the lab industry's top CEOs are saying about the lab and IVD sectors;
- ❑ Improve your bottom line and reduce your risk with two intensive half-day workshops on Coding and Reimbursement for Clinical, Molecular, and Anatomic Pathology and Avoiding the Legal Minefields for Labs;
- ❑ Train your future lab leaders, residents, and administrators at Lab Leaders' Boot Camp, a special all-day seminar in which lab professionals will address six core issues for future managers; and
- ❑ Recognize the industry's leading stars with the presentation of the Washington G-2 Reports' Laboratory Public Service National Leadership Award and the Washington G-2 Report / Dennis Weissman Scholarship Award for Excellence in the Clinical Laboratory Sciences.

To register or get program details, visit *www.g2reports.com/labinstitute08*.

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Applied Biosystems 650-638-5800
Becton, Dickinson 201-847-6800
Bristol-Meyers Squibb 212-546-4000
Clinical Data 617-527-9933
CMS 877-267-2323
CAP 847-832-7000
Clarient 949-425-5700
Dako 45-44-85-95-00
deCODE Genetics 354-570-1900
FDA OIVD 240-276-0450
Invitrogen 760-603-7200
Johnson & Johnson 732-524-0400
LabCorp 800-526-3593
Meridian Bioscience 513-271-3700
Navigenics 866-522-1585.
OraSure 610-882-1820
Rosetta Genomics 201-946-0561
Third Wave Technologies 608-273-8933

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DTTR 8/08

 Diagnostic Testing & Technology Report (ISSN 1531-3786) is published by Washington G-2 Reports, 1 Washington Park, Suite 1300, Newark, NJ 07102-3130. Tel: 973-718-4700. Fax: 973-622-0595. Web site: www.g2reports.com.

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