Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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CONTENTS

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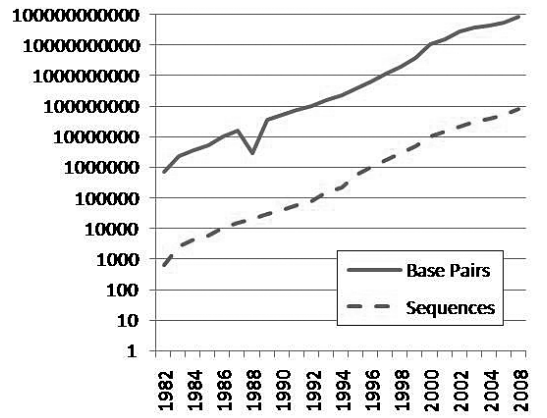
Personal Genomics Raises Questions for IVD Industry

Last year saw the birth of the personal genomics industry, allowing consumers to gain access to their genetic information with varying levels of detail and explanation. Science singled out personal genomics services, now offered by such companies as deCODE Genetics, 23andMe, and Navigenics, as a 2007 "breakthrough of the year," while noting the range of bioethical issues raised by this type of testing. "The most profound implications of having one's genome analyzed may not be what it reveals now—which isn't much—but what it may show later on," wrote Joceyln Kaiser in *Science*.

But the advent of personal genomics may have more immediate ramifications for the in vitro diagnostics and laboratory industries. As it becomes more economically and technologically feasible for anyone to know every letter of their three million base pair genetic alphabet, broad-based genomic profiling performed by direct-to-consumer services such as 23andMe could herald a move away from testing for specific genetic mutations and toward a comprehensive, once-a-lifetime gene scan. For an in-depth look at five companies in this nascent field, see *Inside the Diagnostics Industry*, pp. 5-6.

Growth of GenBank (1982-2008)



* 2008 data as of February 15.
Source: National Center for Biotechnology Information

DCL Medical Laboratories Partners With Third Wave

DCL Medical Laboratories (Indianapolis, Ind.) is teaming up with molecular diagnostics company Third Wave Technologies (Madison, Wis.). The 24-year-old, privately owned reference laboratory, which focuses on women's health, will be Third Wave's product development, demonstration, and marketing partner. According to the terms of the partnership, DCL will adopt products from Third Wave's molecular diagnostic menu and have early access to new assays and equipment developed by the company. Third Wave will also establish a research and development laboratory at DCL for joint product research.

Continued on p. 2

▲ **DCL Medical Laboratories,** *from page 1*

Founded as a fine needle biopsy clinic and cytology laboratory, DCL is now a full-service regional laboratory with operations across the Midwest, including specialty testing in molecular diagnostics. DCL also provides anatomic pathology services in global clinical trials for both pharmaceutical and medical device companies in partnership with central laboratories and clinical research organizations.

Third Wave's 2007 revenues totaled $31.1 million. Clinical molecular diagnostic revenue accounted for $26.3 million of that total, with the remainder from research. The company expects clinical molecular diagnostic revenue to grow to between $33 million and $34.5 million in 2008, an increase of at least 25 percent from last year.

In March, Third Wave received clearance from the U.S. Food & Drug Administration (FDA) for its genotyping test that identifies cystic fibrosis (CF) mutations. The InPlex CF test is Third Wave's second FDA-cleared test. In 2005, it received clearance for its Invader UGT1A1 molecular assay, a pharmacogenomic test that detects variations in a gene that affects the metabolism of such drugs as irinotecan, which is used to treat colorectal cancer. The company is now seeking regulatory approval for its two HPV tests: a 14-type high-risk screening test and a genotyping test for types 16 and 18.

FDA Clears Thermo Fisher's MRSA Test

Thermo Fisher Scientific Inc. (Waltham, Mass.) has received U.S. Food and Drug Administration (FDA) clearance for its Spectra MRSA test designed to screen for methicillin-resistant *Staphylococcus aureus* (MRSA). The test is manufactured, distributed, and sold under the Thermo Fisher specialty brand, Remel.

While a recent study in the *Journal of the American Medical Association* questioned the effectiveness of universal MRSA screening in reducing hospital infection rates, MRSA remains a major concern of health care facilities. According to a recent report by the Association for Professionals in Infection Control and Epidemiology, MRSA is prevalent in 46 of 1,000 patients in the United States.

The Spectra MRSA test consists of a selective chromogenic medium that can be used to detect nasal colonization of MRSA. In the culture medium, MRSA appears as dark blue colonies on a white background. Results are available within 24 hours, and the test has a positive predictive value of 98.1 percent, according to Thermo Fisher.

Fujirebio Diagnostics Buys American Biological Technologies

Fujirebio Diagnostics (Malvern, Penn.), the in vitro diagnostics company owned by Japanese health care company Fujirebio, announced on April 2 that it has acquired American Biological Technologies (ABT; Seguin, Texas), a manufacturer of in vitro diagnostic assay controls and calibrators. The acquisition marks Fujirebio Diagnostics' entrance into the controls and calibrators manufacturing business. Financial terms of the deal were not disclosed.

Fujirebio Diagnostics focuses on cancer diagnostics and biomarker assays. The company has long used ABT as its main supplier of controls and calibrators to confirm that test kits and the analyzers that run the tests are performing to speci-

fications. According to Fujirebio, the acquisition of ABT will result in enhanced, streamlined delivery of material used in products sold to laboratory customers.

ABT's products are designed to work with a variety of diagnostic equipment and in virtually any diagnostic laboratory. Fujirebio Diagnostics plans to exploit this versatility to expand into diagnostics for such conditions as diabetes.

Study Finds Genetic Links to HIV Drug Response

The findings of a new study could lead to the development of pharmacogenomic tests that guide treatment of human immunodeficiency virus (HIV). In a patient outcome study published in the March 30 online edition of *Nature Medicine*, researchers at the Uniformed Services University of the Health Sciences and the University of Texas found compelling evidence that two genes—CCR5 and CCL3L1—are critical in defining the course of immune restoration in HIV-positive individuals undergoing virus-suppressing therapy.

CCR5 is an HIV-1 co-receptor or portal of entry for the virus into CD4+ T cells, and CCL3L1 is an HIV-suppressing molecule that binds to CCR5. The study links variations in these genes to why some subjects' immune systems fail to have a sustained immune comeback, despite suppression of HIV-1 replication by highly active antiretroviral therapy (HAART), while others' immune systems recover rapidly.

The researchers categorized the copy number of the CCL3L1 gene and variations in the CCR5 gene into three groups: high, moderate, and low genetic risk. HIV-positive subjects categorized into the low genetic risk group did the best on HAART, while those in the high genetic risk group did fine in the first two years of therapy, but then their immune reconstitution failed and their CD4 cell counts began to decline.

"The new results suggest that we may be able to personalize the treatment of HIV as we might be able to predict, based on the presence of these gene variations, whether someone will have a better or worse immunological response when taking HAART," said lead author Sunil K. Ahuja, M.D., professor of medicine, microbiology, infectious diseases, and biochemistry at the University of Texas Health Science Center at San Antonio.

A 2005 study led by Ahuja suggested that individuals with fewer than average copies of the CCL3L1 gene have increased risk of acquiring HIV-1 infection and progressing faster to AIDS. Other previous studies by these researchers defined the CCR5 variations that confer protection.

"As those in the high and moderate genetic risk groups might be especially vulnerable to both increased AIDS risk and a poorer immune response during HAART, it might be important to keep a closer eye on such patients and perhaps even consider starting them on therapy earlier," said Brian Agan, M.D., a co-author of the new study.

The study suggests the need for new thinking in HIV management. According to Ahuja, "The current debate about when to initiate antiretroviral therapy might need to be redirected toward first assessing who should be considered for therapy" based on genetic information.

Blood Count, Surgical Path Are Highest Volume Tests for CMS

The most recent data from the Centers for Medicare & Medicaid Services (CMS) reveal that surgical pathology continues to be the highest volume Part B pathology procedure, with approximately 20 million procedures and $1.1 billion in Medicare payments in 2006—well over three times more than any other single procedure in CMS's top 100 lab and pathology procedures, according to Washington G-2 Reports' 2008 Medicare Reimbursement Manual for Laboratory & Pathology Services.

The high volume is due to surgical pathology being one of the few tests where pathologists are reimbursed for a professional component under Medicare, explained Stanley Geyer, M.D., former medical director of the Georgetown University Hospital's Department of Laboratory Medicine (Washington, D.C.), and the founder of Geyer Pathology Services (Pittsburgh). Because physician payments from CMS are decreasing, many pathologists make up that loss of income because of the increased number of biopsy and surgical procedures performed by other specialists that result in increased surgical pathology volume, he explained.

Analysis of the top lab tests found that complete blood count (CBC) topped the high-volume and payment list, with over 30 million in volume and $326 million for Part B lab procedures.

The best paying high-volume tests—defined as one million or more in allowed services—continue to be thyroid stimulating hormone (TSH), with 12.8 million allowed services that paid $298 million in allowed charges and an average of $23.41 per procedure. The lowest average allowed charges per test were serum albumi at $2.07 and direct bilirubin at $2.15.

Overall, spending for Part B lab services furnished in 2006 totaled over $7 billion, accounting for 1.7 percent of total Medicare expenditures. This 2006 total is up 8.7 percent from 2005's total of $6.5 billion. When analyzing hospital-based (outreach and outpatient) spending, CMS spent $3.94 billion in 2006, which represents an increase of almost 15 percent over 2005's spending of $2.95 billion.

Top 10 Medicare Part B Laboratory and Pathology Procedures

Procedure Rank	Code	Allowed Description	Average Services	Allowed Charges	Payment	Allowed Charge
1	85025	Blood count, CBC, auto and auto differential WBC count	30,414,696	$326,626,735.78	$325,622,243.83	$10.74
2	80053	Comprehensive metabolic panel	23,587,089	273,942,183.53	273,403,636.92	11.61
3	85610	Prothrombin time	21,457,089	117,062,500.51	116,737,274.58	5.46
4	80061	Lipid panel	20,273,603	288,598,182.78	288,002,758.36	14.24
5	88305*	Level IV - Surgical pathology, gross and microscopic examination	20,043,366	1,116,944,223.13	870,133,596.37	55.73
6	84443	Assay thyroid stimulating hormone	12,767,124	298,862,318.49	298,419,083.72	23.41
7	83036	Glycosylated hemoglobin test.	10,941,806	147,686,035.59	147,255,635.22	13.50
8	80048	Basic metabolic panel (Calcium, total)	9,906,039	97,469,218.68	97,264,082.53	9.84
9	81000	Urinalysis, nonautomated with microscopy	5,988,320	26,488,773.43	26,301,499.23	4.42
10	81001	Urinalysis, automated with microscopy	5,520,328	24,434,034.92	24,353,088.16	4.43

Source: *2008 Medicare Reimbursement Manual for Laboratory & Pathology Services*, Washington G-2 Reports

As Companies Roll Out Personal Genomics Services, a Look at Five Key Players

In recent months, the media has been abuzz with news of personal genome services offered by companies that provide genetic information directly to consumers. With the help of such well-funded startups as 23andMe and Navigenics (along with a cheek swab and a credit card), now anyone can spend hours Googling his or her own genome for the latest disease-linked single nucleotide polymorphism (SNP) or learn whether they have a risk factor for Alzheimer's disease. Other young companies are developing complementary services, such as genetic counseling and DNA preservation and, in the case of DNA Direct, billing itself as "a Web- and phone-based, virtual genetics clinic." Below, *DTTR* looks at five key players in the emerging personal genomics industry and how they relate to the broader market for in vitro diagnostics.

deCODE Genetics
Headquarters: Reykjavik, Iceland
Founded: 1996
Investors: Publicly traded (ticker: DCGN)
Test: deCODEme
Price: "special introductory price" of $985

Launched last year, the personal genomics service of biopharmaceutical company deCODE Genetics (which also develops, performs, and markets traditional IVD tests through its diagnostics divisions) scans for one million SNPs with a genotyping test carried out in the company's CLIA-certified laboratory in Reykjavik. The deCODEme service includes access to information about ancestry and genetic links to disease, including "updates on how to check your genome against the breakthroughs in the headlines." However, the deCODEme genetic scan does not include genetic variants that have been shown to cause purely genetic diseases or indicate a near certainty of developing any diseases, and the company's Web site emphasizes that deCODEme "is not a clinical service to be used as the basis for making medical decisions." It also notes that subscribers to the service may be eligible for discounts on physician-ordered deCODE diagnostic tests.

23andMe
Headquarters: Mountain View, California
Founded: 2006
Investors: Genentech, Google, New Enterprise Associates
Test: Personal Genome Service
Price: $999 plus shipping

Similar to deCODE, 23andMe offers a genotyping test combined with Web-based reporting. The company uses the Illumina HumanHap550+ BeadChip, which reads more than 550,000 SNPs, plus a custom-designed set that analyzes more than 30,000 additional SNPs. In purchasing the service, customers allow 23andMe to use genetic and phenotypic information for the company's own scientific research and development or that of third parties. Among the IT tools available to users is the Gene Journal, which provides "user-friendly descriptions of the traits we cover and the genes associated with them," as well, as the 23andMe Odds Calculator, which allows us-


23andMe's sample kit.

ers to combine genetic information, age, and ethnicity to get an idea of "the health concerns most likely to affect a person with your genetic profile." In a letter addressed to the medical community, the company notes, "What we do not and will not do is provide medical advice to our customers."

Navigenics
Headquarters: Redwood Shores, California
Founded: 2007
Investors: Kleiner Perkins Caufield and Byers, Sequoia Capital, Mohr Davidow Ventures
Test: Health Compass
Price: $2,500 for initial test and first year's subscription, with an ongoing subscription rate of $250 per year for continuous service

Launched on April 8, Navigenics's Health Compass service scans a person's saliva sample using the Affymetrix Genome-Wide Human SNP Array 6.0, which tests for nearly two million genetic markers, including more than 900,000 SNPs. The service then provides individuals with information and genetic counseling concerning their chances of developing up to 18 common conditions, including breast cancer, Alzheimer's disease, and diabetes. According to the company, users can then use this information "so that with their physicians, they can obtain earlier diagnosis, delay onset, or prevent the conditions altogether."

Knome
Headquarters: Cambridge, Massachusetts
Founded: 2007 (as Cambridge Genomics)
Investors: Privately funded, does not disclose investors
Test: Whole-genome sequencing (now in initial launch phase)
Price: Starts at $350,000

"Knome's goal is to establish the gold standard in personal genomic services for individuals," says CEO Jorge Conde. The new boutique biotech firm is now recruiting a group of approximately 20 clients for full-genome sequencing, making it the first company to commercially offer the service. Rather than evaluating a genome for the presence of predetermined SNPs, whole-genome sequencing decodes the 6 billion bits of information that make up an individual's genome. The company has teamed up with China's Beijing Genomics Institute for sequencing and bioinformatic services, and its first client is Dan Stoicescu, a Swiss millionaire who says that says he will check genetic discoveries against his genome sequence daily, "like a stock portfolio."

DNA Direct
Headquarters: San Francisco, CA
Founded: 2003
Investors: Lemhi Ventures and others
Test: Counseling services for users of personal genomics services, genetic "archiving" (personal DNA storage), and an array of genetic tests, including colon cancer screening (EXACT Sciences's PreGen-Plus assay) and warfarin response testing
Price: Ranges from $150 (pre- or post-testing consultation) to $3456 (full sequencing of BRCA1 and BRCA2 genes)

DNA Direct offers clinical genetic tests directly to consumers, with a "focus on personalized test result interpretation and supportive materials and services." While the company does not offer personal genome scans like those of deCODE or 23andMe, it markets genetic counseling support for these services, including pre- and post-test phone consultations.

Gen-Probe Begins U.S. Clinical Trial of HPV Test

Gen-Probe (San Diego, Calif.) has begun a key U.S. clinical trial of its investigational Aptima assay to detect human papillomavirus (HPV), the virus that causes cervical cancer. The expected trial enrollment of approximately 7,000 subjects at multiple sites and testing are expected to take approximately two years.

Designed to run on Gen-Probe's fully automated, high-throughput TIGRIS instrument system and on the company's medium-throughput instrument platforms, the Aptima HPV assay is an amplified nucleic acid test that detects 14 high-risk HPV types that are associated with cervical cancer. The assay detects two messenger RNAs (mRNAs), E6 and E7, that are made in higher amounts when HPV infections progress toward cervical cancer. Gen-Probe believes that targeting these mRNAs may more accurately identify women at higher risk of having, or developing, cervical cancer than competing assays that target HPV DNA.

Women undergoing routine Pap testing at participating U.S. clinics are eligible to participate in the clinical study, which includes two arms. One arm enrolls women whose Pap results are classified as atypical squamous cells of undetermined significance, meaning they are neither normal nor clearly indicative of changes associated with progression to cervical cancer. In these cases, HPV testing can help determine appropriate medical management. The other arm enrolls women over age 30 whose Pap results are normal. This arm will assess the ability of the Aptima HPV test to identify women who are at greater risk for cervical cancer.

Gen-Probe plans to introduce its Aptima HPV assay as a CE-marked product in Europe in the second half of 2008.

PerkinElmer Appoints Lab Director for Genetic Screening Business

In the wake of its acquisition of the newborn screening business of Pediatrix, PerkinElmer (Waltham, Mass.) is focused on expanding its neonatal, prenatal, and maternal health services businesses. The company has appointed John E. Sherwin, Ph.D., as director of laboratory operations for its genetic screening business. He will be responsible for overseeing and directing the growth of PerkinElmer's genetic screening laboratory services offerings, including neonatal screening reference laboratory PerkinElmer Genetics and NTD Laboratories, a reference laboratory specializing in prenatal risk assessment. Sherwin will report to Ann-Christine Sundell, PerkinElmer's president of genetic screening.

Sherwin joins PerkinElmer from the State of California, where he most recently served as acting chief of the Genetic Disease Branch, responsible for the operation of the State's prenatal and newborn screening program—the largest such program in the world. He has also held positions as senior technical director, general manager, and chief operating officer of large reference laboratories. A past president of both the American Association for Clinical Chemistry and the National Academy of Clinical Biochemistry, Sherwin is a member of the governing council of the International Society for Newborn Screening.

New Approach Reveals Gene Variations Linked to Type 2 Diabetes

Mathematicians at Michigan Technological University (Houghton, Mich.) have developed a novel way to plumb the human genome for single nucleotide polymorphisms (SNPs) linked to complex diseases. Using software based upon an ensemble learning approach (ELA), the researchers can narrow the vast field of candidate genes and then apply statistical methods to determine which SNPs act on their own and which act in combination.

To test their model on real data, the team applied it to a large-scale case-control study for type 2 diabetes. After analyzing genes from over 1,000 people in the United Kingdom, half with type 2 diabetes and half without, the ELA identified 11 SNPs that, singly or in pairs, are linked to the disease with a high degree of probability. Their work was published online earlier this year, in advance of print, in the journal *Genetic Epidemiology*.

While ELA is used to compare the genetic makeup of unrelated individuals to zero in on disease-related genes, the team has also developed a method to examine the genomes of family members going back generations. This approach, published last year in the *European Journal of Human Genetics*, is a two-stage association test that also incorporates founders' phenotypes. "In the past, researchers have dealt with the nuclear family, parents and children, but this could go back to grandparents, great-grandparents . . . as far back as you want," said lead researcher Qiuying Sha.

Obesity Can Deter Women From Cancer Screening

Breast, cervical, and colorectal cancers accounted for 326,290 new cancers cases and 69,850 cancers deaths in 2007 among women in the United States, according to the American Cancer Society.

A review of 32 cancer screening studies (10 breast cancer studies, 14 cervical cancer studies, and 8 colorectal cancer studies) shows that white women who are obese are less likely than non-obese women to get recommended screenings for breast and cervical cancer, according to researchers at the University of North Carolina at Chapel Hill's School of Public Health. The trend was not seen as consistently among black women. The review was published online in the journal *Cancer*.

The most consistent associations reported across all the studies were for cervical cancer screenings, with fewer women getting recommended Pap tests as body mass index increased. The studies showed a stronger trend among white women than black women. The studies also showed lower rates of mammograms among obese white women compared to healthy-weight women. Body size was not consistently related to screening for colorectal cancer among any groups of women in the studies that were reviewed.

"Our review doesn't tell us why larger women are not getting screened as frequently for these cancers," said Sarah S. Cohen, lead author of the review. "It only reveals the trend. We think this pattern should be studied more thoroughly. And in the meantime, some additional effort should be made to reach women at increased risk of cancer because of their body size and to encourage them to get screenings that could save their lives."

CLIA Revises Quality Control Standards, Steps Up Inspections

As the CLIA program marks its 20th anniversary, two significant policy issues will impact laboratories that perform CLIA moderate and high complexity testing: the enforcement of revised quality control standards and tighter lab inspection procedures, in follow-up to recommendations of the Government Accountability Office (GAO).

Updates on these issues were presented by the top CLIA official at the Centers for Medicare & Medicaid Services (CMS), Judy Yost, at a briefing of the Clinical Laboratory Improvement Advisory Committee (CLIAC) during its February 20-21 meeting in Atlanta, and in a March 18 audio conference sponsored by the American Clinical Laboratory Association and also featuring R. Bruce Williams, M.D., who chairs the College of American Pathologists (CAP)'s Lab Accreditation Commission.

In revamping CLIA quality control requirements in 2003, CMS made three major revisions to the Analytic Systems Section affecting verification of performance specifications for moderate complexity tests, clarification of calibration checks, and requiring two levels of external QC every day of testing (with equivalent QC options). Initially, inspectors rated compliance with these revisions via an "educational" approach to help with the transition to testing that was "new to the lab."

But since January of 2008, this approach will continue only for external QC requirements, Yost told CLIAC. CMS will discontinue as "educational" rules for test method verification, maintenance and function checks, and calibration and calibration verification. Labs that do not meet these requirements will be written up for a deficiency and will get a letter requiring corrective action, though CMS could impose sterner sanctions if it thinks serious quality issues are involved.

Yost added one caveat: labs that are CLIA-certified through CLIA-approved accreditation organizations will be required to continue to meet their accrediting body's QC requirements. CMS is working with accrediting bodies to standardize inconsistent policies, she said.

In terms of equivalent QC, Yost noted there was recognition at the 2005 meeting of the Clinical Laboratory & Standards Institute (CLSI) that labs need more information from test manufacturers and that one-size-fits-all QC does not work for different test systems and methods. As a result, CLSI is developing documents on alternative QC for labs and risk management for manufacturers, she said, adding that CMS will revise its interpretive guidelines accordingly, though it has not yet determined if options one to three will remain.

During the ACLA-sponsored audio conference, Yost and Williams discussed their respective programs' actions following criticism from the GAO that lab oversight was not sufficient to ensure quality. The GAO report, issued in 2006, said a better job could be done in problem areas in inspection, complaint, and enforcement procedures and recommended steps to beef up CLIA oversight by CMS and survey organizations.

Yost noted that the GAO made 13 recommendations to CMS with some overlap, so they can be rolled up into 10, she said. CMS disagrees only with the GAO's advice to require proficiency testing four times a year. The agency contends the current method is scientifically valid. It requires proficiency testing three times a year, with five challenges for a test total of 15.

The GAO urged CMS to find ways to compare survey findings across survey organizations, so problems do not fall through the cracks. Yost said CMS is working with its survey partners to collect and compile data for a crosswalk. One issue to resolve is a common definition of "serious deficiency." CLIA recognizes standard-level and condition-level deficiencies, the latter being the most serious, exposing the lab to stricter sanctions. Yet some feel that any deficiency should be regarded as "serious," she observed. Work on the definition is continuing via Partners in Lab Oversight, an initiative to improve information sharing among survey organizations and coordinate follow-up on quality problems.

Top Deficiencies Found in Lab Surveys: Corrective Hints From CMS

- ❑ Don't forget that analytes not listed in the regulations as requiring proficiency testing require a twice yearly accuracy check. Monitor your test menu so you don't miss any.
- ❑ Follow the manufacturer's instructions for test performance, in addition to meeting CLIA quality control requirements. Remember, CLIA supersedes if its requirements are more stringent.
- ❑ Have a quality assurance plan in place, and have it followed for each phase of testing: general, pre, analytic, and post.
- ❑ Include on each test report the day it was issued. This is critical with the advent of e-health records and the pervasiveness of laboratory information systems.
- ❑ Avoid using expired reagents; monitor inventory and workload; develop and follow purchasing and storage policies.
- ❑ Have a procedure manual available for all tests, follow it, and have it signed by the laboratory director. Retain for each procedure for two years following its demise with initial and final dates.
- ❑ Have procedures to monitor specimens from collection to results reporting. Specimen integrity is vital to producing good results.

According to Yost, CMS has agreed to provide no more than two weeks' advance notice to labs it inspects, in line with the GAO's recommendations. CAP and JCAHO have already switched to unannounced inspections, as has COLA for facilities it accredits under its cooperative agreement with JCAHO. As of October 1 this year, CAP will go from a six-month to a three-month window in its inspection program, with a focus on constant preparedness.

Both CMS and CAP have taken steps, Yost and Williams said, to improve the education and training of lab surveyors and to help labs prepare for an inspection, as well as publicize ways to file complaints confidentially, areas the GAO said needed strengthening. And to monitor survey deficiencies, CMS is upgrading the entire CLIA data system so that all entities can track repeat offenders and repeat enforcement actions.

IVD Stocks Gain 4%; Third Wave Climbs 34% on FDA Clearance

The 18 stocks in the G-2 Diagnostic Stock Index rose an average of 4 percent in the five weeks ended April 4, with 10 stocks up in price, six down, and two unchanged. The G-2 index is down 10 percent so far this year, while the S&P 500 has fallen 5 percent and the Nasdaq is down 9 percent.

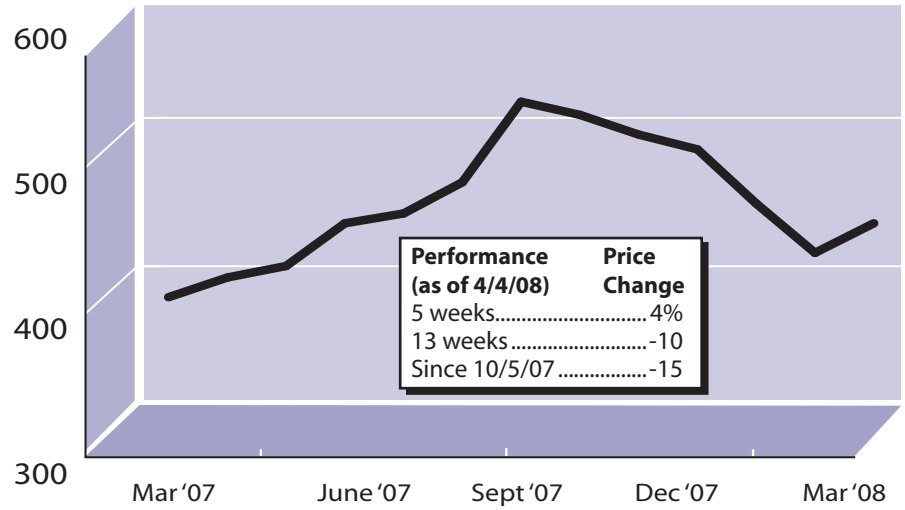
Shares in **Third Wave Technologies** (Madison, Wis.) climbed 34 percent to $9.55 a share for a market capitalization of $413 million. The United States Food and Drug Administration recently cleared Third Wave's molecular test for cystic fibrosis (CF). Using the company's Invader chemistry within a microfluidic card developed in collaboration with 3M, the InPlex CF test simultaneously detects and identifies CF mutations in DNA samples.

Also on the upswing in recent weeks was **Gen-Probe** (San Diego, Calif.). Shares of the molecular diagnostic company were up 10 percent to $51.82 a share for a market capitalization of $2.8 billion. The company recently announced that it has begun a U.S. clinical trial of its Aptima HPV assay, an amplified nucleic acid test that detects 14 high-risk HPV types that are associated with cervical cancer. Gen-Probe shares also got a boost after a Cowen & Co. analyst selected the stock as a top pick in the area of molecular diagnostics, which was singled out as a field in which there is "stunningly strong" investor interest.

Meanwhile, cost cutting continues at **Inverness Medical Innovations** (Waltham, Mass.). In the wake of its decision earlier this year to transfer operations of its Unipath manufacturing facility in Bedford, England, to Asia, Inverness announced that it will close two facilities in the San Francisco area that currently house its Cholestech and HemoSense operations and shutter a manufacturing plant in Louisville, Colorado, that produces its BioStar optical immunoassay (OIA) product lines. The Cholestech and HemoSense operations will be transferred to Inverness's Biosite facility in San Diego, while the company is exiting the BioStar OIA business. Inverness shares were up 9 percent to $32 per share for a market capitalization of $2.6 billion.

For up to the minute laboratory and diagnostic firm data, financial news, and company podcasts—go to **www.g2reports.com**

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
Abbott Labs	$54.84	7%
Beckman Coulter	67.05	3
Gen-Probe	51.82	10
Inverness Medical	32.00	9
Johnson & Johnson	65.73	7
Luminex	20.12	28
Meridian	34.74	9
OraSure	7.55	13
Quidel	16.55	13
Third Wave	9.55	34
Unchanged		
Becton Dickinson	86.07	0
Bio-Rad	88.80	0
Down		
Abaxis	24.77	-8
Affymetrix	17.11	-1
Clinical Data	18.02	-5
Immucor	26.74	-3
Nanogen	0.42	-22
Nanosphere	8.32	-14

G-2 Insider

Don't Gamble on the Future of Your Laboratory Outreach Testing Business . . . Learn from industry leaders at Washington G-2 Reports' seventh annual laboratory outreach conference, which will take place June 18-20 at the Bellagio Hotel in Las Vegas. The premier business event dedicated to improving the performance, profitability, and management of hospital and health system laboratory outreach programs will provide expert advice and practical strategies on such topics as outreach billing and collections, developing outreach sales and marketing plans, building strategic alliances, and using outreach as a strategy for hospital and health system growth, including the following confirmed speakers and sessions:

- ❑ **Priscilla Cherry**, president of laboratory services at Fairview Health Services, will give a keynote presentation on reconstructing an outreach program.
- ❑ Navigant Consulting's **Linda Flynn** and **Bill Evans** will discuss how to determine market potential and market share for an outreach program.
- ❑ **Scott Liff**, vice president of laboratory services and imaging development at John Muir Health System, will address how outreach testing can succeed in a competitive market and contribute to the success of a hospital.
- ❑ Piedmont Medical Labs CEO **Joe Skrisson** and **Gene Heidt** of Central DuPage Hospital will offer advice on how to build outreach connectivity, including the systems available and related costs.

For a full list of sessions or to secure your place at this event, visit *www.g2reports.com* or call 800-401-5937 ext. 3892.

Company References

ACLA 202-637-9466

CAP 800-323-4040

CMS 877-267-2323

DeCODE Genetics 354-570-1900

DCL Medical Laboratories 317-872-0116

DNA Direct 877-646-0222

FujireBio Diagnostics 610-240-3800

Gen-Probe 858-410-8000

Inverness Medical Innovations 800-257-9525

Knome 617-528-1672

Navigenics 650-585-7700

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