Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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JAMA Study Ties BRCA Testing to Favorable Clinical Outcomes

As providers and manufacturers of advanced diagnostic testing look to fill the void of data concerning how test results affect clinical outcomes, a new multicenter study offers an encouraging model. Published in the Sept. 1 issue of the *Journal of the American Medical Association* (*JAMA*), the study found that women at increased risk of breast and ovarian cancer because of inherited mutations of the BRCA1 or BRCA2 genes who underwent prophylactic surgery (mastectomy or salpingo-oophorectomy) had an associated decreased risk of breast cancer and ovarian cancer.

Women who have inherited mutations in the BRCA1 or BRCA2 genes have substantially elevated risks of breast cancer and ovarian cancer, with a lifetime risk of breast cancer of 56 percent to 84 percent. Myriad Genetics (Salt Lake City) offers its flagship BRACAnalysis service to assess BRCA1 and BRCA2 mutation status. Priced at around $3,100, the sequencing test accounted for approximately $320 million in revenue during Myriad's 2010 fiscal year, which ended June 30.

"Measuring clinical outcomes should be a routine aspect of practice," note Laura Esserman, M.D., and Virginia Kaklamani, M.D., D.Sc., in a *JAMA* editorial that accompanies the study. "As physicians begin to adopt computerized data-tracking systems, the goal of such systems should be both to facilitate the rapid introduction of innovations for care and to continually learn about the effects of new and established clinical practices." For more on this story, see *Inside the Diagnostics Industry, p. 5.*

LabCorp to Acquire Genzyme Genetics for $925 Million

Laboratory Corporation of America (LabCorp; Burlington, N.C.) has agreed to pay $925 million for Genzyme Genetics, a business unit of Genzyme (Cambridge, Mass.) that performs reproductive and oncology testing in the United States. Announced on Sept. 13, the transaction is expected to close by the end of 2010.

Specializing in esoteric testing, Genzyme Genetics performs approximately 1.5 million tests per year in its nine clinical laboratories. *Continued on p. 2*

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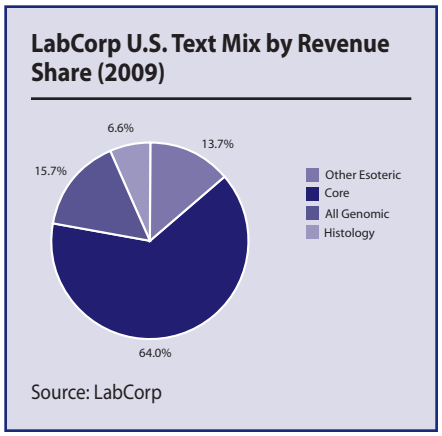
Its offerings range from maternal serum screening and prenatal diagnostics to carrier screening and postnatal testing services. Approximately 70 percent of the business consists of prenatal genetic testing, with the remainder focused on hematology and oncology.



The 20-year-old business, which also fields the nation's largest network of board-certified genetic counselors, reported revenue of $371 million in 2009. This puts the purchase price of the proposed transaction at approximately 2.5 times revenue, similar to the multiple paid by Quest Diagnostics in its 2007 acquisition of AmeriPath.

The announcement of the LabCorp deal comes four months after Genzyme announced its intention to explore "strategic alternatives" for the Genetics business unit as well as its Diagnostic Products and Pharmaceutical intermediates businesses.

Under the terms of the agreement, LabCorp will purchase Genzyme Genetics in its entirety, including all testing services, technology, intellectual property rights, and its nine laboratories. LabCorp has also indicated that it will offer to retain the unit's approximately 1,900 employees, including senior management, when the deal closes.

The all-cash deal would bolster LabCorp's growing esoteric testing business, which in 2009 accounted for just over a third (36 percent) of revenue. The addition of Genzyme Genetics would bring LabCorp's esoteric testing revenue to more than 40 percent.

"This acquisition will substantially expand our capabilities in reproductive, genetic, hematology-oncology, and clinical trials central laboratory testing," said David P. King, chairman and CEO of LabCorp, on a conference call with investors and analysts. "The acquisition of Genzyme Genetics provides us with an unprecedented opportunity for revenue growth in our key strategic focus areas of esoteric testing and personalized medicine."

King went on to emphasize the revenue opportunity that the deal presents rather than the cost reductions that may be realized in combining the companies. "First of all from selling the full LabCorp test menu of approximately 4,400 tests into the existing Genzyme Genetics accounts, secondly offering the Genzyme Genetics brand and capabilities to existing LabCorp accounts," he noted.

Additionally, Genzyme accounts would gain access to LabCorp's network of patient service centers, while LabCorp stands to substantially boost its use of genetic counseling services, which it now offers on a limited basis. On the cost side, specimen collection and logistics are two areas believed to be significantly hindering the profitability of Genzyme Genetics and which LabCorp is expected to focus on immediately following the transaction close.

Lab, Pathology Groups Seek Say as FDA Moves to Regulate Lab-Developed Tests

As the U.S. Food and Drug Administration (FDA) prepares to tighten its regulatory grip on laboratory-developed tests (LDTs), 13 organizations across a broad spectrum of pathology and laboratory medicine providers in clinical and public health lab settings have called for a formal role in crafting a framework for expanded oversight.

In a recent letter to Jeffrey E. Shuren, M.D., J.D., director of the FDA Center for Devices and Radiological Health, the groups asked that the agency "host interactive meetings with stakeholders to discuss specific issues about the framework before [it] moves ahead with any proposal."

Expanded LDT oversight is a complex new initiative, the groups noted, and because of the operational challenges involved for those they represent, they want to be engaged in devising "solutions that will not disrupt innovation, and the value that LDTs bring to patient care and public health needs."

The 13 signatories, which included the American Clinical Laboratory Association and the College of American Pathologists, questioned whether the FDA had the additional resources required to do the job, with thousands of multiple similar, if not identical, LDTs submitted by many clinical labs for review. Oversight should be "clearly defined and balanced, because [it] is already in place by federal, state, and accreditation authorities."

LDTs and test kits requiring premarket review are also operationally different, the groups noted. Clinical labs offering LDTs provide a service, not a test kit that is sold nationwide for use in clinical settings. Another big challenge the groups cited is whether the FDA can implement its plan to increase oversight without disrupting patient access to cutting-edge technology.

Cepheid's Rapid Test for TB Is Clinically Effective, *NEJM* Study Finds

A new rapid automated molecular test to detect tuberculosis (TB) performed well in its first large-scale field trial, according to a study published in the Sept. 9 print edition of the *New England Journal of Medicine* (*NEJM*). The study focused on the dual detection of TB and drug-resistant forms of TB in individuals with and without human immunodeficiency virus (HIV) infection.

Developed by scientists at the UMDNJ-New Jersey Medical School (Newark), Cepheid (Sunnyvale, Calif.), and the Foundation for Innovative New Diagnostics (Geneva, Switzerland), the test is known as the Xpert MTB/RIF test for *Mycobacterium tuberculosis* and resistance to rifampin (RIF). Cepheid markets the CE-marked test, which runs on its GeneXpert System, outside of the United States. It is expected to become available in the United States by 2013.

The *NEJM* study compared the sensitivity and specificity of the Xpert MTB/RIF test to the best available reference standards in the diagnosis of 1,730 patients with suspected drug-sensitive or multi-drug-resistant pulmonary TB at five centers in Peru,

Azerbaijan, South Africa, and India. Researchers found that the Xpert MTB/RIF test diagnosed TB within two hours in 99.2 percent of the patients. Importantly, a single Xpert MTB/RIF test detected TB in 72.5 percent of individuals with TB who did not appear to have TB on conventional microscopic examination, but who were later found to have positive TB cultures.

TB cultures can take as long as six weeks to become positive. The addition of a second and third Xpert MTB/RIF test permitted TB to be detected in 90.2 percent of sputum microscopy-negative individuals. The new test also detected the presence of RIF resistance (a critical marker of multidrug resistance) in 97.6 percent of individuals who were later found to be RIF-resistant on TB culture.

"The test that we developed with Cepheid and FIND finally makes it possible to detect TB in a single clinic visit," said David Alland, M.D., a professor of medicine at UMDNJ and a co-author of the study. "The test also indicates rapidly whether difficult-to-treat drug-resistant forms are present. This is a major advance over other rapid TB detection methods, which are complex, labor-intensive, and technically challenging."

Currently, only a small fraction of the estimated 500,000 patients who have multidrug-resistant TB and 1.37 million patients who have coinfection with tuberculosis and HIV worldwide each year have access to sufficiently sensitive case detection or drug-susceptibility testing.

Celera Patents Association of KIF6 Gene Variant With Heart Attack Risk

The U.S. Patent and Trademark Office has issued a patent to Celera (Alameda, Calif.) for methods of determining heart attack risk by detecting a variant in the KIF6 gene and reducing that risk through statin therapy. The company recently received the CE mark for its KIF6 genotyping assay, which is run on Abbott's m2000 analyzer and will be exclusively marketed by Abbott (Abbott Park, Ill.) outside of the United States.

Research has shown that the patented variant of KIF6 is associated with up to a 55 percent increased risk of primary and recurrent coronary heart disease (CHD). The increased risk of CHD events observed in KIF6 carriers has been shown to be independent of other well-known CHD risk factors, including smoking, hypertension, cholesterol level, age, and sex. Clinical studies have also demonstrated that this increased risk was significantly reduced with atorvastatin and pravastatin, two cholesterol-lowering drugs.

"This patent is an important component of our intellectual property portfolio covering cardiovascular genetics," said CEO Kathy Ordoñez. "And we believe that Celera's growing patent estate should provide our products and services with long-term market protection." Under the company's four-year agreement with Abbott, Celera will manufacture the KIF6 test kit that Abbott will distribute in the European Union, other geographic areas that recognize the CE mark, and elsewhere worldwide, excluding the United States.

Surgical Interventions Based on BRCA Testing Associated With Lower Cancer Risk

Women at increased risk of breast and ovarian cancer because of inherited mutations of the BRCA1 or BRCA2 genes who had prophylactic mastectomy or salpingo-oophorectomy (removal of the fallopian tubes and ovaries) had an associated decreased risk of breast cancer and ovarian cancer, according to a study published in the Sept. 1 issue of the *Journal of the American Medical Association (JAMA)*.

Susan M. Domchek, M.D., of the University of Pennsylvania School of Medicine, and colleagues conducted a study that included a large group of BRCA1/2 mutation carriers to determine cancer reduction estimates following risk-reducing salpingo-oophorectomy and mastectomy, incorporating mutation type and cancer history. The study, which included 2,482 women with BRCA1 or BRCA2 mutations, was conducted at 22 clinical and research genetics centers in Europe and North America. The women were followed up until the end of last year.

The researchers found that risk-reducing mastectomy was associated with a decreased risk of breast cancer in BRCA1/2 mutation carriers, with no breast cancer events occurring in women who underwent risk-reducing mastectomy during three years of prospective follow-up. "In contrast, 7 percent of women without risk-reducing mastectomy over a similar follow-up period were diagnosed with breast cancer," the researchers write.

Risk-reducing salpingo-oophorectomy was associated with a decreased risk of ovarian cancer, with no ovarian cancer events seen during the six years of prospective follow-up in BRCA2 mutation carriers without prior breast cancer who underwent the procedure. Three percent of women without salpingo-oophorectomy over a similar follow-up period were diagnosed with ovarian cancer. No cases of ovarian cancer were diagnosed in BRCA2 mutation carriers after salpingo-oophorectomy, which was also associated with a decreased risk of breast cancer in both BRCA1 and BRCA2 mutation carriers without prior diagnosis of breast cancer.

"Compared with women who did not undergo risk-reducing salpingo-oophorectomy, undergoing salpingo-oophorectomy was associated with lower all-cause mortality (10 percent vs. 3 percent), breast cancer-specific mortality (6 percent vs. 2 percent), and ovarian cancer-specific mortality (3 percent vs. 0.4 percent)," according to the authors.

Laura Esserman, M.D., of the University of California, San Francisco, and Virginia Kaklamani, M.D., D.Sc., of Northwestern University, write in an accompanying editorial that the "discovery of biomarkers that identify high-risk individuals for a specific disease and integration of these biomarkers into clinical practice enables the systematic study of these populations—and development and testing of interventions to reduce their risk."

The editorial also highlighted the need for more studies of clinical outcomes, even with the inherent challenges in standardizing data for these types of investigations. "Better mechanisms are needed to study and evaluate the introduction of new tests, like BRCA gene mutation testing, and to capture key pieces of de-identified information—such as the uptake of testing, results, clinical decisions, and outcomes—so that clinicians and researchers can continually learn from their experience," wrote Esserman and Kaklamani.

Genomic Signature May Help Predict, Monitor TB

Findings from an international study published in the Aug. 19 issue of *Nature* identified changes in the blood that are specific to tuberculosis (TB). The microarray-based research could be translated into a test that can determine which patients infected with the microbes that cause TB will go on to develop the disease.

Researchers examined and compared blood drawn from patients in London, England, and Cape Town, South Africa, who had active TB, latent TB, or who did not have TB. The team developed genomewide transcriptional profiles for each of the patients and discovered a distinct signature of the blood from patients with active TB. The team also found that approximately 14 percent of latent TB patients had signatures similar to those in active TB patients.

"The study shows for the first time that the transcriptional signature in blood correlates with extent of disease in active TB patients," said Octavio Ramilo, M.D., chief of infectious diseases at Nationwide Children's Hospital (Columbus, Ohio) and a co-author of the study. "It validates the idea that this transcriptional signature is an accurate marker of TB infection."

The transcriptional signature was diminished in active TB patients after two months and completely extinguished by 12 months after treatment. "These findings suggest that the blood transcriptional signature of active TB patients could be used to monitor how well a patient's treatment is working," added Ramilo. Longitudinal studies are needed to better assess the marker's utility as a predictive tool.

PET/CT Effectively Detects Breast Cancer Metastases

A recent study suggests that simultaneous positron emission tomography (PET) and computed tomography (CT) scanning can efficiently and effectively detect newly diagnosed breast cancer that has spread to the bone. The findings, published in the June 2010 issue of the *Journal of Clinical Oncology*, suggest a promising way to standardize testing and provide more timely therapy for patients.

Researchers identified 163 women with suspected metastatic breast cancer who had been evaluated by both PET/CT and bone scans at Memorial Sloan-Kettering Cancer Center (New York City) between January 2003 and June 2008. The team compared the images and, when possible, correlated them with confirmatory biopsy results.

The majority of the dual tests were in agreement, leaving just 31 cases (19 percent) conflicting. In only two of these cases did a bone scan reach a positive result when the PET/CT did not, and neither woman received a subsequent confirmation of metastases. Of the remaining mismatched pairs, a majority represented cases of a PET/CT catching tumors that a bone scan missed. The researchers estimate that some metastases could have been discovered by up to three or four months earlier using PET/CT instead of a bone scan. Further, PET/CT uncovered cancer's spread outside the bone in 62 percent of patients in the study.

"If this data holds true in a prospective trial, the issue can be laid to rest and PET/CT could replace CT plus bone scan," notes Maxine Jochelson, M.D., director of radiology at Sloan-Kettering's the Breast and Imaging Center and a co-author of the paper.

Roche Acquires Digital Pathology Firm

Pharmaceutical giant Roche (Basel, Switzerland) is making its move into digital pathology with the purchase of BioImagene, a privately held company based in Sunnyvale, Calif. Roche announced recently that it had signed an agreement under which Ventana Medical Systems, a Roche subsidiary, would pay $100 million for the company, which creates high-resolution, whole-slide digital images from glass microscope slides.

The acquisition will help to cement Roche's dominant position in tissue-based cancer diagnostics, say industry analysts. Roche paid $3.4 billion for Ventana in early 2008 and is now positioning itself to be a leader in digital pathology, which is still in its infancy.

The products that BioImagene provides to anatomic pathology laboratories include its Crescendo workstation, software and companion algorithms, automated digital slide scanners, and an input device for viewing images. LabCorp, Clarient, Bio-Reference, and CorePlus are among the company's U.S. reference lab customers. In May, BioImagene launched its products in Europe, where "demand for digital pathology is at a tipping point," according to CEO Ajit Singh, Ph.D.

AHRQ Links Health Care-Associated Infections to Longer, Costlier Hospital Stays

Adults who developed health care-associated infections (HAIs) due to medical or surgical care while in the hospital in 2007 had to stay an average of 19 days longer than adults who didn't develop an infection, (24 days versus five days), according to a new report from the Agency for Healthcare Research and Quality (AHRQ).

Hospital stays of HAI-infected patients cost an average of $43,000 more than the stays of patients without an HAI.

For patients with an HAI, the rate of death in the hospital, on average, was six times as high as the rate for patients without an HAI (9 percent versus 1.5 percent). Also, on average, the cost of a hospital stay of an adult patient who developed an HAI was about $43,000 more expensive than the stay of a patient without an HAI ($52,096 versus $9,377).

The federal agency also found that in 2007, about 45 percent of patients with HAIs were 65 or older, 33 percent were 45 to 64, and 22 percent were ages 18 to 44. However, the 45- to 64-year-old group had the highest rate of HAIs. Additionally, the top three diagnoses in hospitalized adult patients who developed HAIs were septicemia (12 percent), adult respiratory failure (6 percent), and complications from surgical procedures or medical treatment (4 percent).

The report uses statistics from the 2007 Nationwide Inpatient Sample, a database of hospital inpatient stays that is nationally representative of inpatient stays in all short-term, nonfederal hospitals. The data are drawn from hospitals that comprise 90 percent of all discharges in the United States and include all patients, regardless of insurance type, as well as the uninsured.

CMS Considers Withdrawing Proposed Cytology Proficiency Testing Rule

The Centers for Medicare and Medicaid Services (CMS) is considering withdrawal of its proposal to revise requirements for gynecologic cytology proficiency testing (PT) under the Clinical Laboratory Improvement Amendments (CLIA), the agency said at the Sept. 1-2 meeting of the Clinical Laboratory Improvement Advisory Committee (CLIAC).

That proposal, issued in 2009, was based on most of the recommendations from a CLIAC work group and endorsed by the committee. The changes included lengthening the testing interval, increasing the minimum number of slides (challenges) per testing event, requiring validation of cytology challenges before use in testing, and allowing for new technologies, for example, digital images, as they become available.

"Unfortunately, the current CLIAC members were not members at the time that CLIAC made the original recommendations to CMS for these proposed changes," top CLIA official Judy Yost told Washington G-2 Reports. "Therefore, they were unable to come to agreement about it, even though 77 percent of the comments we received expressed dislike for the rule."

CLIAC has urged CMS to take another look at the comments received on the PT proposal before deciding whether to move forward. Nationwide cytology PT testing began in 2005. Approved providers are CAP and the American Society for Clinical Pathology.

The proposal to revise the PT requirements would impact 2,142 cytology laboratories and 12,831 individuals who screen or interpret 65 million gynecologic cytology preparations in the United States each year, CMS noted. The agency said the program has been successful, based on PT results from the first three years of nationwide testing. For example, failure rates on the initial test of each annual testing cycle dropped from 33 percent in 2005 to 11 percent in 2007 for pathologists reading slides without the assistance of a cytotechnologist.

New Guideline Recommends Universal Newborn Screening for CAH

A new clinical practice guideline released by the Endocrine Society features a series of evidence-based recommendations concerning the diagnosis and treatment of congenital adrenal hyperplasia (CAH). Published in the September 2010 issue of the *Journal of Clinical Endocrinology & Metabolism*, the guideline is endorsed by groups including the American Academy of Pediatrics and the Pediatric Endocrine Society.

CAH is a genetic disorder of the adrenal glands that affects about one in 10,000 to 20,000 newborns. In individuals with CAH, the adrenal glands produce an imbalance of the steroid hormones cortisol, aldosterone, and androgens, which can result in ambiguous genitalia in newborn females, infertility, and rapid growth in both girls and boys before the expected age of puberty.

"If CAH is not recognized and treated, both girls and boys undergo rapid postnatal growth and early sexual development or, in more severe cases, neonatal salt loss and

death," said Phyllis Speiser, M.D., of Cohen Children's Medical Center of New York and Hofstra University School of Medicine and chair of the task force that developed the guideline. "We recommend that every newborn be screened for CAH and that positive results be followed up with confirmatory tests."

In addition to several recommendations from the guideline concerning treatment of CAH, it advises that diagnosis of the condition should rest on clinical and hormone data while genotyping should be reserved for equivocal cases and genetic counseling.

CMS Proposes Requiring Physician Signature on Lab Test Requisitions

Clinical laboratories will face major operational problems if the Centers for Medicare and Medicaid Services (CMS) reverses longstanding Medicare policy and goes ahead with its proposal to require the signature of a physician or a nonphysician practitioner (NPP) on all requisitions for tests paid via the Part B lab fee schedule.

The proposal, announced recently in a proposed rule for the 2011 Medicare physician fee schedule, drew swift opposition from the Clinical Laboratory Coalition, which includes 10 major lab associations. CMS has said it will address stakeholder concerns in the final physician fee schedule that it expects to publish in November.

Currently, under a rule finalized in 2001 and resulting from a congressionally mandated lab-negotiated rulemaking and reiterated by CMS in subsequent manual issuances, a physician's signature is one way to document that the treating doctor ordered the service, but it is not the only permissible way and should not be required as long as such documentation exists in an alternate form. For example, the physician may document the ordering of specific services and their medical necessity in the patient's medical record.

CMS says the approach it is proposing would address concerns raised about the present policy, resulting in a less confusing process and providing a straightforward directive for laboratories to meet. Requiring the signature of a physician or NPP for all requisitions and orders would eliminate "uncertainty over whether the documentation is a requisition or an order, whether the type of test being ordered requires a signature, or which payment system does or does not require a physician or NPP signature."

Nor would it increase the burden on physicians, CMS says. "It is our understanding that, in most instances, physicians are annotating the patient's medical record with either a signature or an initial (the order), as well as a signature on the paperwork that is provided to the clinical diagnostic laboratory that identifies the test or tests to be performed for a patient (the requisition).

"Further, this policy would make it easier for reference laboratory technicians to know whether a test is appropriately requested, and potential compliance problems would be minimized during the course of a subsequent Medicare audit because a signature would be consistently required."

"CMS says this policy will result in less confusion, but it appears to have created the confusion it attempts to minimize in recognizing a distinction between 'orders' and

'requisitions' for clinical lab tests," said attorney Robert E. Mazer with Ober/Kaler in Baltimore. "Complying with this new requirement, if finalized, will be a huge problem for many labs. They won't know what the requirements will be until sometime in November and will then have to have new procedures in place on Jan. 1."

Policy changes may force laboratories to print new requisitions and to educate physicians about new requirements. How the changes will impact electronic ordering arrangements also remains an open question, particularly in light of the fact that many electronic ordering systems are not yet equipped to accommodate an electronic signature.

"I suspect that labs and physicians will strongly disagree with CMS that this requirement would not increase the burden on physicians," noted Mazer. "While physicians may initial or sign the medical record entry, it is unlikely they can sign the requisition at the same time. The requisition requires significant patient demographic information and may not be completed until much later—possibly after the physician has left the office to go on hospital rounds."

First Review Bodies Named to Certify E-Health Records

The Certification Commission for Health Information Technology (CCHIT, Chicago) and the Drummond Group Inc. (DGI; Austin, Texas), have been selected by the HHS Office of the National Coordinator for Health Information Technology as the first technology review bodies authorized to test and certify electronic health record (EHR) systems.

EHR vendors can now begin to have their products certified as meeting the criteria to support "meaningful use," the first stage of which was detailed in a final rule published in July.

In announcing the first certifying bodies, David Blumenthal, national coordinator for health IT, said, "This is a crucial step because it ensures that certified EHR products will be available to support the achievement of the required meaningful use objectives, that these products will be aligned with one another on key standards, and that doctors and hospitals can invest with confidence in these certified systems," he said. Applications from other organizations are under review.

Demonstration of meaningful use of EHRs by physicians and other eligible professionals as well as hospitals is required in order to qualify for new incentive payment programs to help providers switch from paper-based medical records to electronic ones. Individual physicians and other eligible professionals can receive up to $44,000 through Medicare and almost $64,000 through Medicaid.

The certification of e-health records and the financial incentives to adopt and use them effectively is part of a national initiative undertaken by Congress and the Obama administration under the Health Information Technology for Economic and Clinical Health (HITECH) Act, which was part of the American Recovery and Reinvestment Act (ARRA) of 2009.

IVD Stocks Hold Their Ground; Clinical Data Climbs 20%

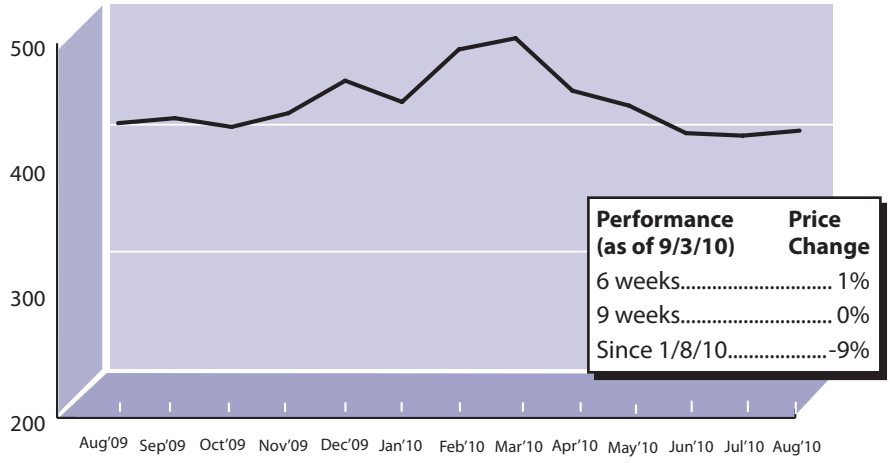
The G-2 Diagnostic Stock Index inched up an average of 1 percent in the six weeks that ended Sept. 3, with 11 stocks up in price, six down, and one unchanged. The G-2 index is down 9 percent since January, while both the S&P 500 and Nasdaq are off 4 percent over the same period.

Clinical Data (Newton, Mass.) soared 20 percent to close at $16.51 per share with a market capitalization of $498 million. The biopharmaceutical company recently announced that revenue for the most recent quarter was up 52 percent to $6.2 million compared to $4.1 million in the same period in 2009. Helping to drive the increase was a 7 percent uptick in revenue from the PGxHealth division's Familion line of genetic tests. The quarter saw the launch of two additional Familion tests, one for conduction disease associated with dilated cardiomyopathy and one for short QT syndrome.

Looking ahead, Clinical Data expects that expanded offerings, greater adoption, and increasing coverage from third-party payers will continue to boost test revenue as it awaits the U.S. Food and Drug Administration's (FDA) decision on its new drug application for vilazodone, a novel anti-depressant. Under the Prescription Drug User Fee Act, the agency has assigned a decision date of Jan. 22, 2011.

Also gaining ground in recent weeks was **Alere** (Waltham, Mass.), the company formerly known as Inverness Medical Innovations. Shares in the company gained 12 percent to close at $30.34 per share with a market capitalization of $2.59 billion. As part of its continued focus on combining rapid diagnostics and health management, Alere recently announced a partnership with AirStrip Technologies (Atlanta) to market the software developer's AirStrip OB. The FDA-cleared application transmits vital patient waveform data, including fetal heart tracing and maternal contraction patterns, directly from the hospital labor and delivery unit to a doctor's mobile wireless device.

G-2 Diagnostic Stock Index



Performance (as of 9/3/10)	Price Change
6 weeks	1%
9 weeks	0%
Since 1/8/10	-9%

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
Abaxis	$19.48	5%
Abbott Labs	50.74	4
Affymetrix	4.47	3
Alere	30.34	12
Becton Dickinson	70.25	6
Cepheid	17.40	5
Clinical Data	16.51	20
Gen-Probe	46.66	8
Johnson & Johnson	58.93	2
Meridian	19.68	1
Sequenom	6.20	6
Unchanged		
Quidel	12.00	0
Down		
Bio-Rad	85.59	-4
Beckman Coulter	46.50	-2
Immucor	18.85	-2
Luminex	15.17	-1
Nanosphere	3.18	-24
OraSure	3.69	-24

G-2 Insider

Agendia and Sequenom add California laboratories . . . Agendia (Amsterdam and Irvine, Calif.) and Sequenom (San Diego) are expanding capacity with new laboratories, both located in Southern California. Agendia recently relocated its U.S. headquarters from Huntington Beach to Irvine with the opening of a 15,000-square-foot genomics laboratory. The new facility will boost capacity to support both the molecular diagnostics company's commercial expansion in the U.S. market and the use of Agendia tests in clinical research.

"Our new genomics lab's capacity will allow us to meet the increasing demand for MammaPrint across the United States," said Bernhard Sixt, Ph.D., president and CEO of Agendia. MammaPrint, Agendia's lead product, was the first test to be cleared by the U.S. Food and Drug Administration as an in vitro diagnostic multivariate index assay (IVDMIA). The 70-gene assay categorizes patients with Stage I/II, lymph node negative breast cancer based on their risk for distant metastasis.

Meanwhile, Sequenom plans to open a genetic testing laboratory in La Jolla later this year, just in time to begin processing samples for a new clinical trial of the company's experimental prenatal test for Down syndrome. The 7,000-square-foot lab is being constructed on the first floor of Sequenom's headquarters. The lab will process 4,000 samples from women participating in a clinical trial of Sequenom's Trisomy 21 (T21) test, which examines nucleic acid from an unborn baby circulating in its mother's blood. The trial is being led by researchers at Women and Infants Hospital, the Brown University affiliate in Providence, R.I.

Company References

Abbott Labs 847-937-6100
ACLA 202-637-9466
AHRQ 301-427-1364
Alere 781-647-3900
CAP 847-832-7000
CCHIT 312-674-4930
Celera 510-749-4200
Cepheid 408-541-4191
Clinical Data 617-527-9933
Drummond Group 817-294-7339
FDA OIVD 301-796-5450
FIND 41-22-710-0590
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