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Competitive Intelligence & Analysis for an Expanding Global Market

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Stakeholders Urge Caution, Collaboration as FDA Moves to Actively Regulate Lab-Developed Tests

Officials from the U.S. Food and Drug Administration (FDA) did much more listening than talking during the two-day public meeting on laboratory-developed tests (LDTs) convened by the agency July 19-20 in Hyattsville, Md. However, it rapidly became clear to the more than 600 people in attendance that it is not a question of if the FDA will exercise its authority over LDTs but when and how. "There are a lot of gaps in the regulations," said Alberto Gutierrez, Ph.D., director of the FDA's Office of In Vitro Diagnostic Device Evaluation and Safety. "Probably the biggest gap of all is clinical validity." While clinical validation is among the FDA requirements for regulation of in vitro diagnostics (IVDs), CLIA requires only analytical validation.

Discussion frequently returned to the differences between the regulatory approaches of CLIA and FDA and the difficulties that complying with FDA IVD requirements would pose to many clinical laboratories that offer LDTs. A variety of presenters and panelists enumerated challenges including meeting FDA Quality System Regulation (QSR) requirements, generating the data necessary for a regulatory submission, and adhering to design controls. Gail Vance, M.D., speaking on behalf of the College of American Pathologists, described LDTs as occupying "a chasm" between FDA and CLIA. "FDA-speak is foreign to labs. We do not have a clue," said Vance. "It's going to take a considerable amount of effort to bridge the CLIA and FDA worlds." For more on the FDA meeting, see *Inside the Diagnostics Industry*, p. 5.

DTC Test Results Are Misleading, Says GAO

Results of direct-to-consumer (DTC) genetic tests are "misleading and of little or no practical use" to consumers, concludes a new report by the Government Accountability Office (GAO). The report was released on July 22 during a hearing on DTC testing before the House Subcommittee on Oversight and Investigations.

GAO investigators purchased 10 tests from each of four DTC genetic testing companies and sent DNA samples (saliva or a cheek swab) from undercover donors to the companies' labs. The companies involved were 23andMe, Navigenics, Pathway Genomics, and deCODE Genetics.

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"Each donor received risk predictions for 15 diseases [selected for comparison by GAO] that varied from company to company, demonstrating that identical DNA samples produced contradictory results," wrote Gregory Kutz, managing director of forensic audits and special investigations at GAO. Results diverged because each company tests for different genetic markers, or single-nucleotide polymorphisms.

The risk prediction-based results received by GAO also sometimes conflicted with diagnosed medical conditions or the family history of the DNA donor. Moreover, the investigators noted that 23andMe provided conflicting predictions for the same DNA within the same results report. The apparent contradiction stems from the company's policy of providing separate reports that draw conclusions based on "established research" and "preliminary research."

In addition, GAO said it discovered 10 incidents of deceptive marketing, including false endorsements and scientifically invalid claims. In its investigation, the GAO recorded representatives from Navigenics telling an undercover donor that she was "in the high risk category of pretty much getting [breast cancer]." GAO also recorded Navigenics representatives claiming that the tests can be used to diagnose diseases.

Following the hearing, 23andMe called the GAO report "deeply flawed" and emphasized the company's strong belief in the value of the data it provides. The company also pointed out that the report focused exclusively on disease risk probabilities and therefore did not take into account other genetic information provided to 23andMe customers, such as ancestry and trait reports, carrier status for single-gene diseases such as cystic fibrosis, and pharmacogenomic data.

IVD Company Iris International to Acquire AlliedPath

Iris International (Chatsworth, Calif.), which manufactures automated in vitro diagnostics systems and consumables for use in clinical laboratories worldwide, has agreed to acquire privately held AlliedPath (San Diego). Iris will pay $4.7 million in cash for the cancer-focused molecular diagnostics laboratory, with an additional $1.3 million payable upon the achievement of specific sales and earnings targets over the next three years. The deal is expected to close by July 30.

The strategic acquisition will provide Iris International with a 10,000-square-foot, CLIA-certified high-complexity molecular pathology laboratory that specializes in solid tumor testing. The company plans to use AlliedPath as "a direct commercial channel for accelerating our ultrasensitive nucleic acid detection immunoassay [NADiA] platform," noted Iris International Chairman and CEO Cesar Garcia.

The first test that Iris International plans to offer through AlliedPath is NADiA ProsVue, a prostate cancer prognostic test designed to identify patients at low risk of cancer recurrence post-radical prostatectomy. The test has been submitted to the U.S. Food and Drug Administration. In addition, Iris believes the laboratory will accelerate the development of additional molecular diagnostic tests.

Founded in 2008, AlliedPath received its California state CLIA license in August 2009. The laboratory's primary customer targets include anatomic pathology groups, hospitals, and regional and community laboratories. Iris plans to expand the CLIA

laboratory's test menu to complement NADiA ProsVue and provide a broader menu of diagnostic panels useful for the diagnosis, disease characterization, treatment, and monitoring of cancer.

AlliedPath currently offers molecular mutation testing for solid tumors, including lung and colorectal cancer, and is expected to add breast cancer by the end of the year. In addition, IRIS is planning to add flow cytometry for detection and monitoring of leukemia and lymphoma as well as fluorescent in situ hybridization (FISH) testing.

Following the acquisition, Vance White, Ph.D., will be appointed corporate vice president of Iris International and president of the new Iris laboratory division. Co-founders Philip J. Ginsburg, M.D., CEO of AlliedPath, and Robin Vedova, president, will join Iris as corporate vice president/chief medical officer of Iris International and vice president of administration of the laboratory division, respectively.

With Eye on IVD Market, Axela Acquires Local Rival Xceed Molecular

Axela (Toronto), which develops systems for multiplex analysis of protein biomarkers, has acquired Xceed Molecular (Toronto and Wellesley, Mass.), which is also focused on translating research discoveries into clinical diagnostic tools. The deal is expected to accelerate Axela's introduction of novel multiplex biomarkers for diagnostics. Financial terms of the transaction were not disclosed.

The combined company, which debuted at the 2010 annual meeting of the American Association of Clinical Chemistry in late July, will offer products for enhanced analysis of proteins, pathogens, DNA, and RNA to speed validation and clinical application of biomarkers. These products include Xceed's Ziplex platform for gene expression analysis as well as its assays for breast cancer and colon cancer.

Axela will now be headquartered at Xceed's former Toronto facility. Rocky Ganske will continue as CEO, with overall responsibility for the company's financial and manufacturing operations, while former Xceed President and CEO David Deems takes over as Axela's president, overseeing sales, marketing, and business development.

"The complementary technologies and content are already well-positioned to improve diagnostics in infection, cancer, and other immune-related diseases," said Deems. "Axela will continue the validation program for Xceed's breast cancer prognostic assay, a gene-expression signature designed to predict risk of recurrence for breast cancer patients." The test is expected to launch commercially in 2011.

All Axela and Xceed products are currently labeled "research use only," but Axela is eager to enter the in vitro diagnostics market with clinical lab-friendly instruments and tests. "Our focus is to simplify multiplex assay development and validation with robust, easy-to-use tools for analysis of DNA, RNA, and protein biomarkers that are designed to move seamlessly from the clinical-research arena into the workflow of the clinical-diagnostics lab," said Ganske.

Novel Primary Care Model Could Reduce Diagnostic Errors

Collaboration and coordination are the keys to reducing costly diagnostic errors, according to an article published in the July 28 issue of the *Journal of the American Medical*

Association. In their commentary, Mark Graber, M.D., of Stony Brook University Medical Center, and Hardeep Singh, M.D., M.P.H., of Baylor College of Medicine, discuss a unique model of primary care, called the patient-centered medical home, and outline five key principles to reduce the incidence of diagnostic errors: Right Teamwork, Right Information Management, Right Measurement and Monitoring, Right Patient Management, and Right Safety Culture.

The model facilitates partnerships between individual patients, their personal physicians, and, when appropriate, the patient's family. Care is assisted by physician "extenders," information technology, and other means to ensure that patient get care when and where they need and want it in a culturally and linguistically appropriate manner.

The medical home model places emphasis on team-based care, and primary care teams could include not only physicians but also nurses and allied health professionals and personnel, the authors explain.

"Task delegation within the 'team' has to be done correctly to avoid errors related to patient follow-up, a common breakdown in the process," said Singh, assistant professor of medicine and health services research at Baylor. For example, monitoring test results, referrals, and appointments to ensure appropriate follow-up could be performed by other team members under physician supervision.

Breakdowns in information management, such as communication and coordination of care, are the root of many diagnostic errors. "Electronic health records can help facilitate information transfer but this information then needs a required follow-up action for the task to be considered completed," noted the authors. "The information loop needs to be closed."

Major issues affecting safe information management are the unclear responsibility for patient follow-up between the primary-care physician and subspecialist or team member, as well as the overwhelming volume of alerts, reminders, and other diagnostic information in electronic health records. The authors recommended that comparative effectiveness studies be undertaken to evaluate which features and functions of electronic records are more effective in reducing diagnostic errors in medical homes.

Improving the current performance monitoring strategies of providers' competence is also necessary, the researchers pointed out, including better measurement processes and outcomes related to compliance with preventive measures and key indicators of diagnostic performance. "Newer methods that include electronic surveillance and monitoring techniques could be used to detect diagnostic errors proactively," wrote the authors. "These approaches could be accompanied by feedback to clinicians about specific prevention strategies."

The current conversation about the patient-centered medical home is focused on reimbursement and chronic disease care, Singh and Graber noted. "But patient safety must be a central, organizing principle and not just an afterthought," they advised. "From a practical standpoint, this necessitates an appropriate infrastructure and skill set to ensure effective implementation of the four rights described above."

inside the diagnostics industry

FDA Convenes Public Meeting on Oversight of Lab-Developed Tests

As the line between laboratory-developed tests (LDTs) and medical devices subject to premarket regulatory review has grown ever blurrier, the U.S. Food and Drug Administration (FDA) recently announced its intention to move to a risk-based application of LDT oversight. How that goal will be accomplished remains to be seen, but the agency heard a variety of suggestions, concerns, and frustrations at the two-day public meeting it convened on July 19 in Hyattsville, Md.

Approximately 600 stakeholders, including laboratory professionals, clinicians, and industry representatives, packed the auditorium of the Marriott Inn and Conference Center at University of Maryland University College for a series of public presentations and panel discussions on patient and clinical considerations concerning LDT oversight, clinical laboratory challenges, direct-to-consumer testing, and education and outreach.

"Although FDA has decided to exercise its authority over laboratory-developed tests, we have not made any decisions about how to exercise that authority," said Jeffrey E. Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health, in his opening statement. "That's what this two-day meeting is about."

"We see LDT being used more and more as a loophole," said FDA's Elizabeth Mansfield. "Preliminary medical data is being packaged as medical information."

Moving to Unify a Bifurcated Approach

LDTs and diagnostic test kits are subject to different standards and uneven enforcement, the FDA has acknowledged. Courtney Harper, Ph.D., of the FDA's Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), described the current regulatory strategy as bifurcated, with commercially distributed tests and LDTs taking divergent paths to market.

The proportion of tests taking the LDT route, which does not require FDA submission, has climbed in the past 10 to 15 years, she said, and the volume and variety of LDTs has grown exponentially. The self-determined nature of LDT status is also problematic, noted Harper. "An LDT is not always lab-developed."

Commercially offering LDTs through a CLIA-certified laboratory created specifically for that purpose is now frequently used as a mechanism for market entry, allowing novel tests to reach the national market without going through the FDA. "We see LDT being used more and more as a loophole," said Elizabeth Mansfield, Ph.D., director for personalized medicine at FDA OIVD. "Preliminary medical data is being packaged as medical information."

In a presentation that provided historical context concerning FDA's approach to LDTs, Courtney Harper, Ph.D., director of the agency's division of chemistry and toxicology devices, noted that "CLIA regulation of laboratories and FDA regulation of tests are complementary for diagnostic testing." She went on to compare the regulatory approaches (see table), highlighting the FDA requirements for clinicial validation and design control.

Weighing the Risks and Benefits

The FDA's move to actively regulate this class of in vitro diagnostics (IVDs), which are

manufactured and offered within a single clinical laboratory, is a response to public health risks created by LDTs that may not provide a reasonable assurance of safety and effectiveness.

"Laboratories are laboratories, not manufacturers," said ACLA President Alan Mertz. "We are a service provider."

"The goal of regulation is to maximize value and minimize risk," said Principal Deputy FDA Commissioner Joshua M. Sharfstein, M.D. "We really do want to foster innovation in testing while ensuring high quality."

Many public commenters also focused on risks, including those of stifling innovation among test developers, depriving patients and clinicians of critical diagnostic information, burdening the small clinical laboratories for whom the LDT designation was originally designed, and overtaxing the limited resources of the FDA.

"Market forces are very efficient at determining use of LDTs," said Benjamin Salisbury, Ph.D., vice president of clinical genetics of the PGxHealth division of Clinical Data (Newton, Mass.), which offers a line of genetic tests as LDTs. "Underutilization, not overutilization, is the norm. Clinicians and payers are traditionally slow adopters until there is consensus in the medical community on clinical utility."

He concluded with the example of PGxHealth's recently launched tests for inherited heart conditions through its CLIA-certified lab in New Haven, Conn. "We wouldn't have [introduced these tests] if we had to go through FDA," Salisbury said. "We want to be able to be able to react as quickly as the science will allow."

Many of the presenters at the meeting urged FDA to undertake in-depth research on many fronts before proceeding with draft guidance. Industry consultant Mary Pendergast was one of many attendees who suggested that the agency thoroughly examine how clinicians and patients are using LDTs and how they understand the results.

"We have to go forward in a very measured way, identify gaps, and fully understand what's at stake," said Alan Mertz, president of the American Clinical Laboratory Association, who called for a broad grandfather exception for existing, established tests. "Laboratories are laboratories, not manufacturers. We are a service provider."

Looking Beyond FDA for Solutions

FDA representatives conceded that they have no clear idea of the scope of the LDT market that they are seeking to regulate and suggested that efforts to learn who is offering what tests would be coordinated with the National Institutes of Health, which recently announced its plan to develop a genetic testing registry.

"There are thousands of LDTs out there. Most have been offered safely and efficaciously for many years," said Gail Vance, M.D., representing the College of American Pathologists (CAP). "If I were the FDA, I would start by gathering data. Get to know the universe—CAP, CLIA. It's going to take a considerable amount of effort to bridge the CLIA and FDA worlds."

Possible roles for third-party organizations in LDT regulation figured prominently in the two-day discussion, with presenters and panelists referring to regulatory schemes proposed by groups including CAP and AdvaMed. In highlighting CAP's 2009 proposal

to clarify oversight of LDTs, Vance emphasized the potential value of a risk-based approach that would be realized through "a partnership between [the Centers for Medicare and Medicaid Services], FDA, and third-party accreditors."

	FDA	CMS (CLIA)
Registration/Listing	Registration of establishment Publicly available listing of marketed tests	Registration and certification of lab lists of tests maintained by CMS (not currently publicly accessible)
Analytical validation	Premarket review of analytical data for Class II and Class III tests	Sampling after marketing during periodic laboratory inspections
Clinical validation	Premarket review of clinical claims for Class II and Class III tests; post-market surveillance of clinical claims for Class I tests	Not required
Quality system	GMPs, QS regulations assessed by inspection	Laboratory quality system assessed by inspection
Design controls	Required for Class II and Class III tests and all other devices with software	Not required Software not addressed by CLIA
Adverse event reporting	Yes	No
Post-market surveillance	Yes	No
Recalls	Yes	No

Source: FDA OIVD

A collaborative solution was also favored by Judy Yost, director of laboratory services at CMS and head of the CLIA program. "A public-private partnership is probably a good way to go," she said. "We clearly offer the resources of CMS and CLIA to assist in this process." FDA's Mansfield said that the agency was considering using CLIA inspectors for the LDT inspection process.

Other commenters expressed concern at stepping up LDT oversight without first reassessing the system for reimbursement of laboratory tests. While acknowledging that reimbursement is outside FDA jurisdiction, Michael Stocum, managing director of the consulting firm Personalized Medicine Partners (Raleigh, N.C.), called for "a move toward value-based reimbursement that would reduce the bias toward an LDT solution." He also suggested that the FDA facilitate cooperation with expanded regulation by making available FDA-accepted sample repositories with clinical data and expanding the availability of test standardization programs.

"We'll get a lot out of this," said Alberto Gutierrez, Ph.D., director of FDA OIVD, who in his concluding statement described the meeting as "very rich."

The FDA has said that it will review comments from the meeting, as well as those submitted to the docket by Aug. 15, and develop a draft oversight framework for public comment "with the goal of providing a level of predictability as quickly as possible." Such a framework would likely be phased in over time based on the level of risk of the test.

Gen-Probe Gets FDA Clearance for Prodesse Flu Test

The U.S. Food and Drug Administration has cleared for marketing the Prodesse ProFast+ assay, a molecular diagnostic test that can detect and differentiate among three common influenza A virus subtypes: seasonal A/H1, seasonal A/H3, and 2009 H1N1. The test is manufactured and marketed by Gen-Probe (San Diego), which acquired Prodesse in October 2009 for approximately $60 million plus potential milestone payments of up to $25 million.

Knowing which influenza subtype a patient has can assist clinicians in selecting treatment, as each subtype has a different susceptibility to commonly used influenza antiviral drugs.

The ProFast+ assay is a multiplex, real-time reverse transcriptase polymerase chain reaction (RT-PCR)-based in vitro diagnostic test that qualitatively detects influenza A from nasopharyngeal swabs. It uses the same internal control and format as the three other FDA-cleared Prodesse tests for respiratory infectious diseases. Test results are available in approximately four hours.

In addition to making the test available as an FDA-cleared kit, Gen-Probe will continue to offer real-time RT-PCR-based influenza A subtyping through the Prodesse CLIA-certified laboratory in Waukesha, Wis. Gen-Probe's pricing for this lab testing service ranges from $60 to $150 per test, depending on the sample type.

Study Compares Prognostic Tests for Kidney Disease

A morning urine test is superior to all other tests for detecting declining kidney performance in patients with diabetic kidney disease, according to a study published on July 15 in the online version of the *Journal of the American Society of Nephrology*. The results suggest that the best available approach to monitoring kidney function is by measuring the albumin-to-creatinine ratio from a first morning urine sample.

Individuals with kidney dysfunction often excrete excess protein in the urine (proteinuria). Screening for this condition may help identify people at risk for kidney disease progression, but uncertainties persist as to how urine should be collected and which specific urinary proteins should be measured.

Researchers from the University Medical Center Groningen in the Netherlands assessed and compared the ability of various proteinuria measures to predict worsening kidney problems. Albuminuria, a large component of proteinuria, is more specific than total proteinuria and is defined as an excess amount of albumin in the urine. Four measures were compared: urinary protein excretion from a 24-hour urine collection, urinary albumin excretion from a 24-hour urine collection, urinary albumin concentration from a first morning urine sample, and albumin-to-creatinine ratio from a first morning urine sample.

The investigators conducted their analysis in 701 patients with type 2 diabetes and kidney disease who were participating in a clinical trial. They defined worsening kidney function as the development of end-stage renal disease or a doubling of blood levels of

creatinine, which is a breakdown product of muscle creatine. Kidney dysfunction diminishes the ability to filter creatinine, resulting in a rise in blood creatinine levels.

Measuring the albumin-to-creatinine ratio in a first morning urine sample emerged as the superior method to predict kidney problems in patients with type 2 diabetes and kidney disease. "From a clinical point of view, these results are very important, because they imply that collection of first morning voids, which is clearly more convenient than collecting a 24-hour urine, can be used for assessment of proteinuria," said Hiddo Lambers Heerspink, Pharm.D., Ph.D., lead author the study. The authors also noted that standardizing proteinuria measures will improve methods for detecting and monitoring kidney disease.

Illumina Acquires Helixis, Launches Novel PCR Platform

Genetic analysis company Illumina (San Diego) has acquired Helixis (Carlsbad, Calif.), a developer of high-performance, low-cost, real-time polymerase chain reaction (PCR) systems, for $70 million in cash and up to $35 million in payments contingent upon the achievement of revenue-based milestones through the end of next year. Helixis CEO Alex Dickinson has joined Illumina as senior vice president of PCR Solutions.

Illumina announced the completed acquisition on July 27 along with its financial results for the second quarter of 2010. The day also marked the launch of the company's Eco system, a novel real-time PCR platform that is currently aimed at the research market. The benchtop instrument was developed by Helixis.

"The U.S. list price [for the Eco system] is $13,900, which is approximately a quarter of the price of systems in the market with comparable performance," said President and CEO Jay Flatley on a conference call with analysts and investors. "We believe the combination of performance features and market disruptive pricing makes this a system ideal for personal use in the [research] laboratory."

Initially the Eco system will run most commercially available quantitative PCR chemistries, but Illumina plans to develop and market proprietary consumable kits that are specifically designed for the platform.

Study Highlights Variability of Leading Cholesterol Tests

A study published in the June issue of *Clinical Chemistry* found that seven leading commercial methods of directly measuring cholesterol levels produce results of mixed accuracy when compared to ultracentrifugation reference measurement procedures, which are used as the basis for clinical guidelines.

Many commercially available tests for determining HDL-cholesterol (HDL-C) and LDL-cholesterol (LDL-C) use surfactants, ionic polymers, and other components that either selectively prevent or enable measurements of cholesterol in specific classes of lipoproteins among the full range of lipoprotein particles present in serum. There has been some concern whether these direct lipoprotein cholesterol methods generate values equivalent to those of older methods and to the established reference measurement procedures for HDL-C and LDL-C.

A research team led by W. Greg Miller, Ph.D., of Virginia Commonwealth University evaluated seven commercially available direct measurement reagents for quantifying HDL-C and LDL-C. The team examined 175 patients in all—37 with no known disease and 138 with known cardiovascular disease and other conditions such as dyslipidemia—and compared the results to those obtained by reference measurement procedures. They evaluated trueness, accuracy for individual samples, imprecision, and specificity for HDL and LDL lipoproteins.

"In the nondiseased individuals, six of eight HDL-C and five of eight LDL-C direct methods met the National Cholesterol Education Program [guidelines]," said research team member Elizabeth T. Leary, Ph.D., chief scientific officer at Pacific Biomarkers (Seattle). "However, all the methods failed to meet the NCEP's goals for diseased individuals, because of compromised specificity toward abnormal proteins." NCEP guidelines assess the accuracy of methods for measuring patient cholesterol levels.

Homogeneous methods can suffer from nonspecificity in unusual samples, such as lipoproteins that altered as in certain diseases or after some drug treatments. "As observed in the study, all methods are more variable in diseased samples," noted Leary. "The fact is that no method can be 'correct' all of the time including the 'reference methods.' It all depends on the definition of truth. The bottom line is that one needs to know the assays, use them appropriately, and interpret the data accordingly."

CMS Issues Final Rules Related to 'Meaningful Use' Program

On July 13, the Centers for Medicare and Medicaid Services (CMS) issued two final rules to implement a program to incentivize physicians and hospitals to adopt and make "meaningful use" of certified electronic health record (EHR) technology. The meaningful use rule specifies the objectives that providers must meet in payment years 2011 and 2012 to qualify for incentive payments. The certification rule specifies the technical capabilities that EHR technology must have to be certified and to support providers in meeting meaningful use criteria.

According to economic analysis by CMS, incentive payments under Medicare and Medicaid EHR programs from 2011 to 2019 will range from $9.7 billion to $27.4 billion. The financial incentives were approved as part of the economic stimulus package in a bid to jump-start public and private collaboration leading to a nationwide system of electronic health records that will achieve health, quality, and efficiency goals.

The CMS rule affects direct incentive payments to pathologists in independent practice and hospital-based pathologists who practice primarily in ambulatory settings.

While the incentive program is voluntary, there are penalties for eligible professionals who do not participate and fail to meet meaningful use requirements. Their Medicare reimbursement will be reduced by 1 percent beginning in 2015 and in subsequent years by up to 5 percent.

Meaningful use criteria will be phased in over the next several years in three stages, beginning with the collection of electronic health data in coded formats, reporting of the health information that can be used to track key clinical conditions, and implementation of structured data exchange.

IVD Stocks Hold Steady; Beckman Coulter, Affymetrix Tumble

The G-2 Diagnostic Stock Index fell less than 1 percent in the three weeks that ended July 23, with 10 stocks up in price and eight down. The G-2 index is down by 10 percent since January, while the S&P 500 has dropped 4 percent and the Nasdaq is off 2 percent over the same period.

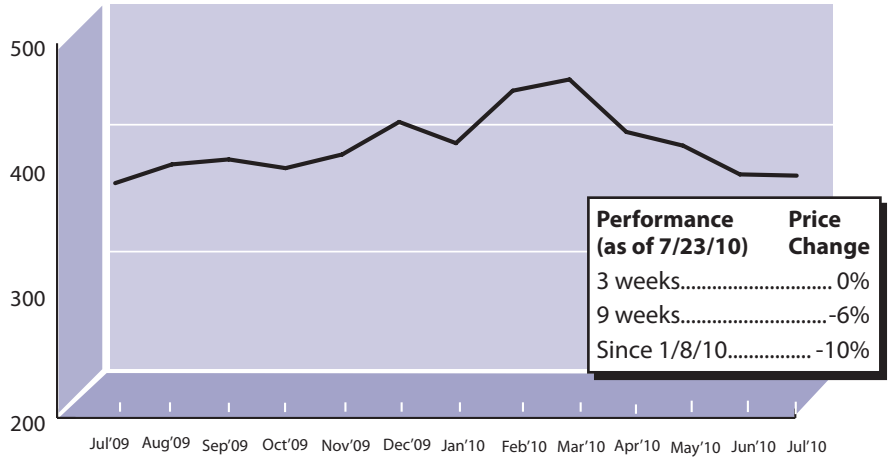
Beckman Coulter (Brea, Calif.) plummeted 23 percent to close at $47.26 per share with a market capitalization of $3.25 billion. Shares sank after the company reported a 27 percent drop in profits for the second quarter. Beckman also lowered its full-year earnings outlook from $4.30 to $4.50 per share to between $3.90 and $4 per share. Management attributed the lowered full-year expectations to "quality challenges in the U.S. market, weakness in demand from life science markets, and reduced expectations for our cellular business."

Beckman's quarterly revenue of $902 million, which included $116.6 million from its recent acquisition of Olympus Diagnostics, also disappointed analysts, who had pegged it at $929.7 million. The clinical diagnostics division was one of few bright spots, with second-quarter revenues increasing 21.5 percent (in constant currency) due to Olympus and robust growth in the Asia Pacific region.

Also losing ground in recent weeks was **Affymetrix** (Santa Clara, Calif.). Shares in the microarray maker plummeted 26 percent to close at $4.33 per share with a market capitalization of $357 million. For the second quarter of 2010, the company reported total revenue of $71.7 million as compared to $81.6 million for the same period last year. The 12 percent drop from the prior year was primarily driven by a drop in scientific services, which the company is now outsourcing.

Affymetrix recently granted a worldwide license to Signature Diagnostics, a German company that will use Affy microarray technology to develop and commercialize diagnostic and prognostic colorectal cancer tests.

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	$48.93	6%
Bio-Rad	89.38	4
Cepheid	16.54	7
Clinical Data	13.75	15
Immucor	19.30	4
Inverness Medical	27.07	5
Meridian	19.48	13
Nanosphere	4.20	2
OraSure	4.86	9
Sequenom	5.84	4
Down		
Affymetrix	4.33	-26
Abaxis	18.57	-12
Beckman Coulter	47.26	-23
Becton Dickinson	66.89	-2
Gen-Probe	43.10	-7
Johnson & Johnson	57.63	-2
Luminex	15.30	-7
Quidel	11.98	-3

G-2 Insider

Preventive medicine gets $9 million boost from HHS . . . Department of Health and Human Services (HHS) Secretary Kathleen Sebelius has announced 15 awards totaling $9 million to support preventive medicine residency programs at accredited schools of public health, schools of medicine, and hospitals. Of these funds, nearly $6.7 million is part of the $200 million appropriated to HHS' Health Resources and Services Administration (HRSA) under the American Recovery and Reinvestment Act of 2009 to address the nation's health care workforce shortages.

HRSA's Preventive Medicine Residency Program provides support to develop new residency programs; maintain, improve, and expand existing programs; and provide financial support to trainees in these programs. Over the next three years, it is projected that more than 180 preventive medicine residents will receive training in public health settings including hospitals, community health centers, industrial sites, and academic centers.

California makes headway on lab workforce shortage . . . In the five years since its founding, California's Healthcare Laboratory Workforce Initiative (HLWI) has helped to more than double the number of hospitals that provide on-site clinical training for aspiring laboratory science workers. Completing such training is required to become a licensed clinical laboratory scientist or medical laboratory technician in California. The HLWI, an initiative of the Hospital Council of Northern and Central California that is supported by the Abbott Fund, has also helped to ensure hospital training sites expand their programs to allow for more students.

Company References

23andMe 650-938-6300
Affymetrix 408-731-5000
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ACLA 202-637-9466
Axela 416-798-1625
Beckman Coulter
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CAP 847-832-7000
Clinical Data 617-527-9933
CMS 410-786-3000
deCODE Genetics
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