G2 INTELLIGENCE

Diagnostic Testing &Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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Vacancies in Lab Staffing: Molecular and Automation Shifting Needed Skills

According to the American Society for Clinical Pathology's newly released *2011 Vacancy Survey of U.S. Clinical Laboratories*, blood banking and transfusion medicine laboratories are experiencing the highest overall vacancy rates at more than 11 percent, followed by histology departments with a vacancy rate of almost 10 percent. Cytology and immunology departments have the lowest rates at just over 5 percent.

The survey of more than 625 facilities found outpatient clinics and hospitals with 100 beds or less reported the highest vacancy rates, as did laboratories in the West. Shortages are expected to continue as the number of retirements across all departments increases in coming years. Immunology faces the highest percentage of expected retirements in the next five years.

As molecular diagnostics continues to penetrate clinical laboratories, there will be a shift in required skills. The survey found nearly a quarter of facilities have one central molecular diagnostics lab, while 21 percent of facilities report molecular diagnostics are performed within specific laboratory departments. The majority of laboratories cite "lack of necessary education and skills to perform the work" as the primary reason for recruitment difficulty. But as advances in automation and genomics continue to evolve, necessary workforce skills will be redefined. For more on drivers and trends in laboratory automation, please see *Inside the Diagnostics Industry* on p. 5.

Companies Plan Stock Buybacks, Increase Returns to Investors

Flush with cash and improving optimism about the state of the economy, firms throughout the diagnostics industry have announced a series of stock buybacks. Since the start of the year, companies like Illumina (San Diego), Thermo Fisher Scientific (Waltham, Mass.), Myriad Genetics (Salt Lake City), Gen-Probe (San Diego), and Life Technologies (Carlsbad, Calif.) have all agreed to buy back anywhere from $100 million to $750 million worth of common stock in an attempt to put their cash to work to increase shareholder value.

"In 2009 everybody battened down the hatches," says Peter McDonald, a vice president and research analyst at Auriga USA. "With increasing cash flow

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▲ **Companies Plan Stock Buybacks,** *from page 1*

they have room on their balance sheets but don't want to institute dividends. So stock buybacks are another way to return to investors."

In mid-March Illumina announced it will spend up to $425 million in net proceeds from an offering of $800 million in convertible senior notes to repurchase about 4.9 million shares of its common stock. Gen-Probe also launched a $150 million buyback of its 48.5 million shares of common stock in mid-February.

Recent Share Repurchases

- In late February Thermo Fisher Scientific announced its board had authorized a new $750 million share repurchase program on top of an existing $750 million program initiated in September 2010.
- Life Technologies said in January it will repurchase up to $500 million of its 186.7 million shares of outstanding common stock.
- In March Myriad Genetics announced plans to repurchase $100 million of its shares, marking its third such program in the last year.

"Based on our healthy balance sheet and strong anticipated cash flows, we believe we can increase long-term shareholder value and offset dilution from employee option programs by buying back stock, while at the same time retaining the strategic and operational flexibility to invest appropriately in our business," said Herm Rosenman, Gen-Probe's chief financial officer, in a statement.

While acquisitions have picked up throughout the diagnostics and laboratory industry, in some cases companies are holding off on acquisitions until the right opportunity comes along.

"All of these companies are very selective in their acquisitions strategies," says McDonald. "They don't want to do an acquisition far afield, and rolling up companies has not always worked well [in this industry]. If it doesn't fit, they'll just pull down shares."

Following a hiatus in 2008 and 2009, McDonald predicts the industry will continue to see companies announce plans for more stock buybacks. "Boards seem to like it. Investors are OK with it," McDonald tells *DTTR*. "They will keep cash on hand, enough dry powder in case [an acquisition opportunity presents itself], but they will be continually pulling in shares."

N.Y. Approves Quest's ColoVantage CRC Blood Test

Quest Diagnostics' (Madison, N.J.) ColoVantage test for colorectal cancer (CRC) was approved by New York state's Department of Health in March. The company claims it is the first molecular CRC detection method that employs a venal blood specimen to be approved by the state.

The test detects methylated DNA of the Septin9 gene from blood taken from a patient's arm. The Septin9 biomarker has shown consistent CRC detection in several case-control studies. According to Quest, the test has an overall sensitivity of 70 percent and 89 percent specificity. The biomarker was licensed to Quest Diagnostics by Epigenomics AG (Frankfurt, Germany) in 2008.

Unlike other CRC tests, ColoVantage does not require dietary restrictions or special preparations, and testing can be added to routine blood work. While not a replacement for colonoscopies, ColoVantage is designed to aid in the detection of CRC in patients who resist testing by guideline-recommended screening methods. The test has not been validated for screening in the general population.

CDC Finds Lack of Evidence for LabCorp's ColoSure Test for General Screening

In a review published last month in the online journal *PLoS Currents*, researchers from the Centers for Disease Control and Prevention (CDC) found no evidence to support the use of LabCorp's (Burlington, N.C.) ColoSure test in the general population.

While it does not contain a recommendation, the report is intended to inform the Evaluation of Genomic Applications in Practice and Prevention working group and will help decide if a full evidence review of fecal DNA testing for colorectal cancer (CRC) is warranted. ColoSure is the only commercially available fecal DNA test for CRC.

The laboratory-developed test detects a single marker, the methylation of the vimentin gene. Studies have demonstrated that the vimentin gene is not or is rarely methylated in normal colonic epithelial cells but is methylated in colorectal cancer and adenomas. According to LabCorp, ColoSure's sensitivity varies between 72 percent and 77 percent in patients with known invasive colorectal cancer, and its specificity rages from 83 percent to 94 percent.

The at-home test requires a physician prescription, but the researchers determined they could not determine the test's analytic validity, clinical validity, or clinical utility from available literature. Additionally only case-control studies were published, fueling uncertainty about the validity of vimentin as a biomarker for CRC screening in the general, average-risk population for which colonoscopies remain the gold standard.

"The CDC is not in a position to dictate clinical protocols," said Renee Ned, Ph.D., health scientist, CDC's Office of Public Health Genomics. "There is not enough evidence to say one way or the other if it should be used for population-based CRC screening."

Experts remain optimistic that if it is integrated into colorectal cancer screening strategies, the noninvasive fecal DNA test may improve adherence for preventive screenings for CRC. According to the CDC in 2008, the latest year for which data are available, only about 62 percent of men and women aged 50 to 75 reported getting the most commonly recommended CRC screening tests.

Half of Labs Performing Molecular Diagnostics: Considerations in Starting an MDx Lab

A survey conducted by the American Society for Clinical Pathology (ASCP) found that just over 47 percent of responding clinical laboratory departments do not perform molecular diagnostics. Of those that do, it is split nearly evenly (25 percent and 22 percent, respectively) between labs that have a central molecular diagnostics department and facilities that have molecular diagnostics performed within specific laboratory departments.

While growth of molecular diagnostics is outpacing overall lab growth, driven in part by both its cache and its high margins, there are many considerations to bringing molecular testing in-house. Starting a molecular diagnostics (MDx) lab was a much-discussed topic at G2 Intelligence's 2011 MDx Conference, held in Boston April 13-15, where Gyorgy Abel, M.D., Ph.D., director of clinical immunology and molecular

diagnostics/clinical chemistry at the Lahey Clinic (Burlington, Mass.), laid out some fundamentals that should be addressed when assessing the feasibility of molecular genetics.

Gather Information: Check monthly send-out reports, consult clinicians in your institution, follow clinical guidelines, and know your institution's strategic plan.

Understand True Costs and Needs: Understand the true costs per test, and consider reagent rental vs. capital purchase and clinicians' turnaround time needs. Assess personnel readiness and work flow. Consider cross-training laboratory staff.

Building a Test Menu: The adage "If you build it, they will come" is not necessarily true, warns Abel. Build a test menu based on the information gathered and base volumes on existing data. Infectious disease testing (including tests that detect, quantify, and genotype) currently drives the molecular diagnostics market. These are generally good tests to introduce first as they are usually high-volume tests.

Communicate: Inform and educate clinicians of new tests through e-mails, rounds, or lunchtime presentations; consult; and offer clear reporting.

Sensitive Troponin With Lower Threshold Improves Outcomes

Lowering the threshold of plasma troponin assays can improve clinical outcomes by identifying patients at high risk for recurrent myocardial infarction (MI) or death. According to a study published in March in the *Journal of the American Medical Association*, the diagnostic reclassification of patients resulting from implementation of this assay improved clinical management and outcomes, including decreased hospital admissions for recurrent MI.

The researchers studied 2,092 patients with suspected acute coronary syndrome (ACS; heart attack and unstable angina) admitted to the Royal Infirmary of Edinburgh (Scotland) for both the validation phase and the implementation of this assay. MI was determined, in part, with evidence of myocardial necrosis using plasma troponin concentrations of 0.05 ng/mL. The original diagnostic threshold was 0.20 ng/mL.

In patients presenting with suspected ACS, the use of a sensitive troponin I assay increased the detection of MI by 29 percent. During the validation phase, 39 percent of patients with plasma troponin concentrations of 0.05 to 0.19 ng/mL died or had recurrent MI at one year compared with 7 percent and 24 percent of those patients with troponin concentrations of less than 0.05 ng/mL or more than 0.20 ng/mL, respectively. During the implementation phase, lowering the diagnostic threshold to 0.05 ng/mL was associated with a lower risk of death and recurrent MI (from 39 percent to 21 percent) in patients with troponin concentrations of 0.05 to 0.19 ng/mL.

In the study, patients with an undisclosed, small troponin elevation (0.05 to 0.19 ng/mL) had poor outcomes. These patients were less likely to receive treatment, despite having evidence of MI on the electrocardiogram, demonstrating the heavy reliance placed by clinicians on the plasma troponin assay concentration in the modern management of patients with suspected ACS. Lowering the diagnostic threshold for MI was associated with an increase in the use of evidence-based therapies and a 50 percent reduction in death or recurrent MI in the group of patients with increases in plasma troponin assay concentration levels below the previous diagnostic threshold.

Advanced Automation Penetrating Labs; Prior Process Improvement a Must

Automation has transformed laboratory medicine from a fully manual practice to one in which laboratories have analyzers that are now capable of performing hundreds of laboratory tests in an automated format. From the first installations of total automation systems in the mid-1990s, there are now an estimated 800 laboratories worldwide with automated systems. Automated systems and practices are expected to penetrate all clinical labs of every size in the coming years.

While the promise of improved quality, quicker turnaround times, and increased staff productivity lures laboratories to examine automated systems, experts say current attention to automation is brought on by increasing staffing shortages and increasing testing volumes generated through consolidation of services into central laboratories, along with an aging population.

"The trend is clearly all labs are undergoing some type of automation," says John Crissman, M.D., CEO of Integrated Laboratory Automation Solutions Inc. (Troy, Mich.). "With decreasing FTE and fewer and fewer med techs, you must use them more efficiently and not use them on low-tech functions."

The staffing shortages can inevitably lead to stress on the job and high turnover, which fuel human errors. From compromised streaking patterns to contaminated cultures, improper media selection, or specimen identification errors, properly implemented and loaded automated solutions can reduce laboratory errors.

"Humans make mistakes," says Paul Bourbeau, Ph.D., director of microbiology laboratories at Geisinger Medical Laboratories (Danville, Pa.) "Instruments are more reproducible. Instruments don't take coffee breaks or vacations."

Most common automation applications have been applied to centrifugation, aliquotting, and the interfacing to analyzers for serum chemistry, immunoassay, hematology, and coagulation tests. While certainly an exceptional example in both scale and the scope of development of its groundbreaking automation systems, ARUP Laboratories (Salt Lake City) illustrates a successful implementation of automation.

Leading Edge of Automation

As a national clinical and anatomic pathology reference laboratory, ARUP has different needs than a typical clinical laboratory that has a high concentration of a handful of tests. According to ARUP, it takes more than 1,000 different tests to comprise 80 percent of ARUP's test volume, with many of these tests being infrequent, manual tests performed in small batches.

ARUP's automation focuses on the elimination of excessive handling and sorting, improved tracking, storage and retrieval of specimens for repeat or additional testing, and real-time communication among all of ARUP's laboratory-related software systems.

The lab credits the automation with improved quality, turnaround time efficiency, and profitability, including reduction of lost specimens by 80 percent, reduction of turnaround times by 30 percent, and a doubling of productivity.

Whether at ARUP or a small hospital lab, poor laboratory processes may function faster with automation, but they are still poor processes, says Charles D. Hawker, Ph.D., ARUP's scientific director of automation and special projects. ARUP's success with its automation efforts lies in the other process improvements implemented in conjunction with automation including the adoption of a standardized transfer tube, the consolidation of higher-volume testing in an automated core laboratory, the development of a new rules-based, intelligent order-entry and support software system (Expert Specimen Processing), and the redesign of the specimen processing workstations to be used with the automated transport and sorting system (referred to as the Automated Track System for short).

Will Automation Trickle Down?

So, can smaller labs benefit from automation?

"There is a misunderstanding that you need automation only in big labs. It is just the opposite," says Crissman. "Small labs can benefit very much from automation. The large Quests have been using automation for decades. Eventually it will work its way down to every lab in time."

Highlights of ARUP Automation

- ❏ The lab's 1,100 foot transport and sorting system has a capacity of 8,000 specimens per hour.
- ❏ ARUP's two-story freezer automated storage and retrieval system (Daifuku America Corp.) holds more than 2.3 million specimens and can retrieve individual specimens requests in 2.5 minutes for 38 employees simultaneously.
- ❏ ARUP's Storage AutoSorter (Advanced Technology Services Inc.) is capable of sorting 4,000 specimens per hour.

But, experts warn, labs looking to automation need to be realistic and value-minded. "Don't automate just for the sake of automation. Look at the business decision," says Robert Boorstein, M.D., Ph.D., medical director Enzo Clinical Labs, a full-service clinical reference laboratory in Farmingdale, N.Y. "There are two big errors of the past. Automation is not a cure-all. It is part of the solution, but with IT issues or old instruments, automation doesn't help you. The other mistake is building a large, automated platform on the prediction of future growth. I've seen labs with 10 times bigger equipment than they need. It is a lot of capital up front and by the time they fill it, the equipment will be obsolete."

Experts believe some labs have not embraced automation both because of local challenges such as physical constraints and capital challenges, as well as more global impediments including a health care system that traditionally has not rewarded improving efficiencies in care delivery.

"Some labs in older facilities or separate rooms don't have the physical capabilities of putting it in without a huge renovation, so it's not a lack of desire," explains Wayne D. Mercer, Ph.D., a senior consultant, operations management at Chi Solutions (Ann Arbor, Mich.).

Renovations and the equipment necessary require large capital investments that are certainly harder to come by during down economic times. But the return on investment for automation solutions, when carefully implemented, is fairly quick. Some say the bigger challenge comes from the broader health delivery system.

> ***"There will be a change in health care delivery to improve efficiency rather than attracting more patients because eventually you will run out of new patients."***
> ***– John Crissman, M.D.***

"All hospitals have capital problems," says Crissman. "They want to spend money on another MRI machine. There will be a change in health care delivery to improve efficiency rather than attracting more patients because eventually you will run out of new patients. But we are not yet at that point."

"Health care reform has not embraced automation," adds Robin Felder, Ph.D., a professor of pathology and associate director of clinical chemistry and toxicology at University of Virginia School of Medicine. "It has punitive measures, but it hasn't thought about incentives like comprehensive automation. In my opinion, we can reduce 30 percent of health care costs by leveraging process management and automation."

Felder explains that capital investments don't have to be made all at once, but laboratories can begin with "islands of automation that can be linked over time." While a piecemeal approach is often sensible, directors exploring automation options must face the divide in the industry between open and closed systems.

"We are seeing many lab managers and directors that still like to select the best vendor system for each technical discipline," says Mercer. "The perception out there is that one vendor is better than another's technical capabilities for a specific discipline."

But not all automated systems allow mismatched analyzers. "There is a big fight in the industry," explains Crissman. "Will labs stand for being dictated to what type of analyzer to use in their lab? . . . Some say, OK, we'll use all Beckman. Some want open systems so they can pick and choose. It is a big question mark, but I think we will end up with a little bit of both."

Looking to the Future

Whichever system directors choose, the experts *DTTR* spoke to say the future of automation will be cheaper, faster, and simpler.

"[Some companies] build huge analyzers [capable of running] 100 different tests. But most of the time 20 tests are being run on it—20 most common tests account for 85 percent of daily utilization," says Crissman. "So we will return back to simplicity—high-speed, less-expensive analyzers for routine tests."

Other predictions include a migration to liquid microbiology specimens, says Bourbeau, and possibly even telemicrobiology. "After a specimen is processed and conveyored into an incubator, and scanned by cameras, you can look at pictures of plates on a computer. Maybe you'll never touch a plate."

Three Markers in Routine Lab Test Predict Progression in Kidney Patients

A triple-marker approach for identifying chronic kidney disease (CKD) improves prediction of end-stage kidney disease and all-cause death, as compared to measuring creatinine, according to a new study. The study, published in the *Journal of the American Medical Association* in April, shows that improved risk stratification achieved through utilizing a renal panel that combines creatinine, cystatin C, and urine albumin-to-creatinine ratio (ACR) could improve the delivery of care by both reducing unnecessary workups for low-risk individuals and prioritizing specialty care and interventions for individuals at highest risk.

The 26,643 participants were registered for the Reasons for Geographic and Racial Differences in Stroke study. Overall, 2,904 participants (11 percent) were classified as having CKD based on creatinine or a combination of creatinine and the other markers. But among the 23,739 participants with no CKD defined by creatinine, 3,863 (16 percent) had CKD detected by ACR, cystatin C, or both.

The researchers found that adding cystatin C to creatinine and albuminuria could more accurately reclassify patients and better distinguish prognostic differences, namely a threefold risk of death and fourfold risk of end-stage renal disease. Cystatin C and albuminuria were both strongly and independently associated with all-cause death among persons with or without CKD defined by creatinine-based estimated glomerular filtration rate.

"The risk of future end-stage renal disease was concentrated within the subset of participants who had CKD defined by all three markers," wrote the authors. "The second highest risk group for end-stage renal disease was missed by creatinine, but was detected by cystatin C and ACR."

The authors note that several groups currently revising international guidelines to more accurately reflect prognosis of CKD complications have proposed adding ACR to staging of CKD. Currently, routine assessment for ACR is only recommended for persons with diabetes. Initial CKD detection in is primarily limited to serum creatinine testing. Cystatin C is available but is not routinely used in clinical practice in the United States.

LabCorp, Qiagen, Quest Continue Acquisitions

April saw continued consolidations in both the laboratory and the diagnostics industries. LabCorp, Qiagen, and Quest have announced acquisitions that further expand their access to proprietary biomarker pipelines and esoteric testing menus.

LabCorp Buys Orchid Cellmark

LabCorp (Burlington, N.C.) announced its intent to buy Orchid Cellmark (Princeton, N.J.), a forensic and family relationship DNA testing services company for approximately $85.4 million in the beginning of April. The acquisition strengthens LabCorp's presence in identity testing and establishes a presence for identity testing in the United Kingdom. The deal is expected to close in the second quarter of 2011.

Orchid Cellmark provides DNA forensic testing services for the criminal justice sys-

tem and provides family relations testing for both child services organizations and individuals seeking parentage verification. In 2010, Orchid Cellmark posted revenues of $63.7 million, an 8 percent increase over 2009's revenue of $59.1 million. LabCorp will acquire Cellmark's 30.5 million fully diluted outstanding shares including options for $2.80 per share, or roughly 1.3 times revenues.

Qiagen Acquires Cellestis' 'Premolecular' Testing Technology

Also in the beginning of April, Qiagen (Venlo, Netherlands) agreed to buy Cellestis (Melbourne, Australia) for $355 million in cash. Qiagen gains access to Cellestis' QuantiFeron technology for detecting cell-mediated immune responses of T-cell lymphocytes using whole-blood samples. Tests based on this "premolecular" testing technology can provide information on latent infections before DNA-based tests can detect the low amount of pathogens present.

Cellestis has two commercially available products, which Qiagen believes have both untapped market potential and the ability to drive traditional DNA-based molecular diagnostics for subsequent testing or monitoring. Cellestis' flagship product is the Food and Drug Administration-approved QuantiFeron-TB Gold-in-Tube (QFT) test for latent tuberculosis, which launched in 2006 and accounts for the majority of current sales. The QuantiFeron technology will be adapted for use with Qiagen's ESE detection technology, a mobile device that runs on battery power allowing the QFT test to be used in areas lacking access to a laboratory.

Cellestis' Quantiferon-CMV test for cytomegalovirus (CMV) complements Qiagen's DNA-based molecular diagnostic tests for CMV viral load and is expected to be synergistic with Qiagen's test for transplantation medicine.

In fiscal 2010 ending June 30, 2010, Cellestis posted revenues of $42 million, a 17 percent increase over 2009. On an adjusted basis, the purchase is anticipated to be mildly dilutive to Qiagen's full-year 2011 earnings per share (EPS), due to large investments in sales and research and development initiatives related to the migration of Cellestis' products to Qiagen's QIAsymphony and QIAensemble platforms and for new product development. For 2012 Qiagen said that it expects double-digit sales growth from QuantiFeron products and accretion of 2 cents to 3 cents per share to EPS.

Celera's Berkley HeartLab to Merge With Quest

Quest Diagnostics' $344 million acquisition of Celera (Alameda, Calif.) cleared antitrust review and is expected to close at the end of April. The deal announced in late March gives Quest (Madison, N.J.) immediate access to proprietary genetic tests and a pipeline of biomarkers heavy in cardiovascular (CV) disease and cancer, which the company expects to drive sustainable growth.

Quest will buy Celera's outstanding stock for $8 per share in cash, but the transaction value is expected to be further reduced through the realization of a significant portion of Celera's available tax credit, net operating carry-forward losses, and capitalized research and development, which totaled $117 million at the end of 2010. Celera generated revenues of $128 million in 2010.

"Our discovery and validation of new biomarkers has exceeded our capacity to commercialize them," said Kathy Ordoñez, CEO of Celera, in a statement. "Combining Celera's expertise in genetics with Quest Diagnostics' medical leadership, market access, and scale is expected to speed the realization of our vision to personalize medicine."

The HeartLab's testing includes HDL and LDL analysis to characterize CV disease risk and KIF6, 9p21, and LPA genotyping to assess risk and therapy response. Quest secured fully committed bridge financing for the transaction, and assuming an April close, Quest Diagnostics expects Celera to add just over 1 percent to its 2011 revenue growth.

Japanese Disaster: Diagnostics Face Small Exposure

More than a month after the 9.0 earthquake and tsunami that ravaged Japan, life science companies have moved beyond initial damage assessments and are focusing on reorganizing logistics and strategic operations in light of utilities and transportation disruptions during what will be a lengthy rebuilding process.

Japan represents the third-largest market for health care and medical devices, with an estimated 13,000 employees of American medical device and diagnostic companies in Japan, according to the Advanced Medical Technology Association.

"The clinical diagnostic companies in my universe have very little direct exposure to Japan, though I am sure that the disruption of the entire electronics supply chain will have some impact on manufacturing their instruments," says Jonathan Groberg, an analyst at Macquarie Securities (Sydney, Australia).

As the industry tries to assess the impact for the remainder of 2011 and beyond, analysts expect impacts to be relatively small and affect companies nonuniformly.

Given laboratories may be shut down, "we would expect consumable companies to be at more near-term risk," wrote Groberg in a research note. "Instrument manufacturers could be at more mid-term risk given their reliance on electronic components should electronic supply chains remain disrupted, though longer-term customers are again likely to replace broken or damaged equipment." Groberg compiled the Japanese revenue exposure for the following diagnostics and life science companies:

- Agilent Technologies Inc. (Santa Clara, Calif.) has 11 percent Japanese revenue exposure and has manufacturing and research and development facilities west of Tokyo that were "unaffected."
- Life Technologies (Carlsbad, Calif.) has 10 percent Japanese revenue exposure. The Ion Torrent supply chain was "not impacted," but a Hitachi plant that manufactures the CE and SOLiD 5500 instruments was damaged.
- Affymetrix (Santa Clara, Calif.) has approximately 7 percent Japanese revenue exposure but less than 2 percent Japanese facility exposure.
- Becton Dickinson's (Franklin Lakes, N.J.) Japanese sales totaled 5 percent of total fiscal-year 2010 revenues. The company reported that their plant in Fukushima was partially operational as of April 5 and repairs are under way to repair additional manufacturing lines in the facility.
- Illumina (San Diego) faces a 5 percent revenue exposure in Japan. Groberg stated that he believes certain optical components may be provided by suppliers in Japan.
- PerkinElmer Inc. (Waltham, Mass.) faces approximately 5 percent Japanese revenue exposure, primarily in analytic instruments and biodiscovery activity.

IVD Stocks Jump; Cepheid Reports Gains in First-Quarter Revenue

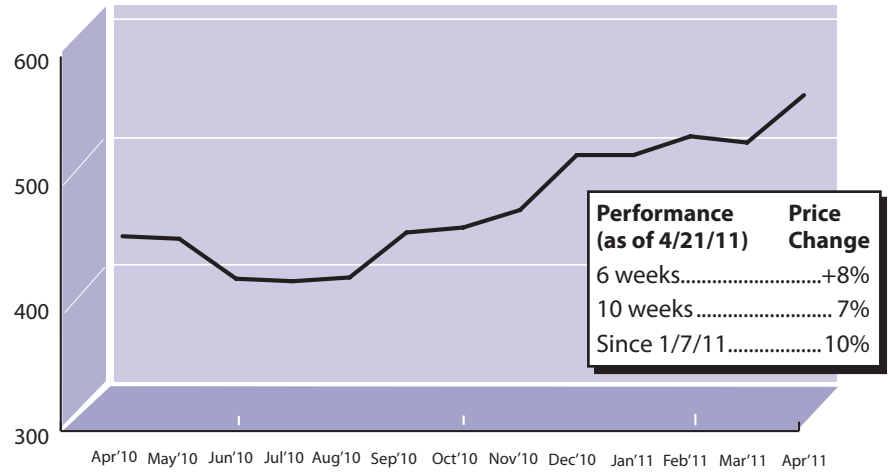
The G2 Diagnostics Stock Index was up 8 percent for the six weeks ending April 21, with 17 stocks up in price and two unchanged. The G2 Index outperformed both the Nasdaq and the S&P over the same period, with both of those indexes up 4 percent and 3 percent, respectively.

Cepheid's (Sunnyvale, Calif.) stock was up 20 percent, driven by the company's positive first quarter. The company reported first-quarter revenue for 2011 of $60.2 million, up from $48 million for the first quarter of 2010. Net income was $0.5 million compared to a net loss of $4.3 million in the first quarter of 2010. For the 2011 fiscal year the company expects total revenue in the range of $245 million to $255 million. Continued growth for the GeneXpert molecular platform contributed to the positive revenue reports. The company also announced that it received clearance from the U.S. Food and Drug Administration (FDA) to market its Xpert C. difficile/Epi test, which builds on a previous test that detects the bacterium that causes C. difficile infection as well as the epidemic strain of C. difficile, also known as 027, NAP1, or BI.

Affymetrix (Santa Clara, Alif.) shares increased 17 percent to $5.74. The company continues to expand its Axiom product line with the recent launch of the Axiom Genome-Wide CHB 1 Array, the first commercial product to maximize genetic coverage of common alleles in Han Chinese populations. This array is the third population-designed array for the Axiom Genotyping Solution and one of several arrays commercialized this year.

OraSure Technologies (Bethlehem, Pa.), whose stock gained 23 percent in the past six weeks, submitted to the FDA an application for a CLIA waiver for its OraQuick HCV Rapid Antibody Test. The test for the detection of antibodies to the hepatitis C virus received FDA approval in late February. It is currently classified as a moderately complex test that can be used by approximately 40,000 laboratories. If the CLIA waiver application is approved, the OraQuick HCV test could be available for use at more than 180,000 sites nationwide, including labs at outreach clinics, community-based organizations, and physician offices.

G2 Diagnostic Stock Index



Source: The G2 Diagnostic Stock Index is tabulated weekly by *DTTR* from the average percentage change in the stock price of 19 IVD companies.

Up	Price	% Chg
Abbott Labs	$51.80	7%
Abaxis	29.00	3
Affymetrix	5.74	17
Alere	38.71	5
BectonDickinson	84.00	7
Bio-Rad	120.91	4
Cepheid	31.46	20
Gen-Probe	69.90	8
Illumina	69.90	8
Immucor	20.98	9
IRIS	9.16	2
Johnson & Johnson	64.07	7
Luminex	18.99	4
Meridian	24.55	14
OraSure	8.50	23
Qiagen	20.63	2
Sequenom	7.24	27
Unchanged		
Beckman Coulter	83.03	0
Quidel	12.15	0

G2 Insider

Limited Reimbursement Hampers Novel Diagnostics. . . A report commissioned by the Biotechnology Industry Organization and written by Health Advances (Weston, Mass.), a health care industry strategy firm, found that limitations in the current reimbursement system lead to inconsistent coverage, restrict patient access, and impede the investment necessary for the development of the generation diagnostics.

In the report, "The Reimbursement Landscape for Novel Diagnostics: Current Limitations, Real-World Impact, and Proposed Solutions," the authors advocate for reform that increases transparency, consistency, and speed for the coverage of novel diagnostics. They seek a solution that would "fairly compensate diagnostics based on standardized value justifications, while limiting incremental cost to the system." Through a series of interviews with senior leaders in payer, provider, government, investment, and diagnostics organizations, the authors determined that coverage of diagnostics is nonuniform, in part because of inconsistent payer evaluation processes. The report says coverage decisions for novel diagnostics are made "ad hoc," often in response to physician demand. Also, the diagnostics industry does not have a clear set of expectations for the level of evidence necessary for reimbursement, including clinical trial requirements.

The report is available at *www.bio.org/healthcare/personalized/Health_Advances&BIO_Novel_Diagnostics_Reimburs_20110103.pdf.*

"The current reimbursement system was designed to support relatively simple diagnostic tests that formed the basis of the traditional diagnostics industry," write the authors. "The system was not designed to support novel complex diagnostics, and . . . despite the clinical and economic value of these technologies as the foundation of personalized medicine, payers have not reformed their systems."

Citing "waning" investment in the diagnostics industry in part due to the "uncertain reimbursement environment" the authors suggest a continuum of reform efforts: from niche solutions (establishing a set of test-specific codes, companion diagnostic bundled payment, and economic study standards for novel diagnostics) to moderate solutions (managed entry, coverage with evidence development risk-sharing payment schemes) and broad reforms (value assessment body for novel diagnostics).

Company References

Abbott Laboratories 847-937-6100
Affymetrix 408-731-5000
Agilent Technologies 408-345-8886
ARUP Labs 800-522-2787
Becton Dickinson 201-847-6800
Cepheid 408-541-4191
Enzo Clinical Labs 631-755-5500
Gen-Probe 858-410-8000
Illumina 800-809-4566
Integrated Laboratory Automation Solutions 248-742-9155
LabCorp 336-229-1127
Life Technologies 760-603-7200
Myriad Genetics 801-584-3600
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