Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

Issue 11-03/March 2011

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Qiagen Invests for Access to Markers

Qiagen (Hilden, Germany) will acquire a minority stake in Alacris Theranostics GmbH, a German start-up that specializes in deep sequencing. The investment provides Qiagen with an exclusive option for access to all biomarkers discovered in this collaboration. Financial details of the agreement, which was announced in January, were not disclosed, but the company said that Alacris will receive royalty fees for the commercialization of these biomarkers.

Alacris uses a proprietary modeling system, ModCell, to identify clinically relevant molecular targets from vast amounts of genetic data. Selected markers can be formatted into commercializable PCR-based assays that yield data to stratify patient populations in clinical trials and for therapy guidance.

"Our strategic investment in Alacris expands Qiagen's existing broad biomarker discovery and validation initiatives and is designed to expand our QIAsymphony-based personalized health care and pharma development assay portfolio," said Peer Schatz, CEO of Qiagen.

The company is currently active in more than 20 projects with major pharmaceutical companies to develop companion diagnostics and is actively collaborating on the discovery and validation of biomarkers. For more on Qiagen's future growth, see *Inside the Diagnostics Industry, p. 5.*

Danaher to Acquire Beckman Coulter for $6.8 billion

Genoptix and Epicentre Biotech Also Find Buyers

In the largest deal of the past year, Danaher Corp. (Washington, D.C.) announced it will acquire Beckman Coulter Inc. (Brea, Calif.) for $6.8 billion.

Beckman Coulter would become part of Danaher's Life Sciences and Diagnostics segment, expanding Danaher's presence in the testing market and boosting its health care revenues to roughly 47 percent of total sales, which had $2.3 billion in revenue in 2010. The deal, announced on Feb. 7, is expected to be completed in the first half of 2011.

Danaher agreed to purchase Beckman's stock at a price of $83.50 per share, a 45 percent premium to the closing price of Beckman Coulter's stock on Dec. 9, 2010, prior to speculation about the firm being put up for sale. The deal will be financed through on-hand cash (25 percent of purchase price), new and assumed debt (60 percent), and equity (15 percent).

Continued on p. 2

▲ **Danaher to Acquire Beckman Coulter,** *from page 1*

Beckman had a challenging year in 2010. Following the summer recall of its AccuTnl troponin test, which the U.S. Food and Drug Administration accused the company of improperly marketing, the company lowered its full-year 2010 revenue expectations. CEO Scott Garrett resigned in September. The announced purchase price represents 1.8 times revenue. Although Beckman Coulter has not yet released its earnings for the fourth quarter or full year 2010, Larry Culp, president and CEO of Danaher, said during a recent conference call that Beckman generated about $3.7 billion in revenues last year.

In the call Culp noted Beckman Coulter's strong presence in China, where it has the number two position in the in vitro diagnostics space with more than $300 million in revenues, growing at 25 percent annually.

In a month in which acquisition activity typified the trend of consolidation in the IVD testing industry, other key deals also were announced.

Novartis to Acquire Genoptix

Swiss pharmaceutical company Novartis agreed to acquire Genoptix (Carlsbad, Calif.) in an all-cash tender offer valued at $470 million, or $25 per share. The acquisition will expedite the development of companion diagnostics aimed at improving health outcomes through personalized medicine, especially in the field of oncology.

Genoptix, a specialized laboratory providing personalized diagnostic services to community-based hematologists and oncologists, specializes in diagnosing cancers in bone marrow, blood, and lymph nodes. Its laboratory service offerings provide a "strategic fit" with the current portfolio of companion diagnostic programs within Novartis's molecular diagnostics unit.

The purchase price represents approximately 2.4 times Genoptix's estimated 2010 revenue of $196 million. Genoptix failed to meet revenue expectations in the spring of 2010 and its stock price never recovered from a high of $30. The deal is expected to close within the first half of 2011.

Illumina to Buy Epicentre Biotech

Illumina (San Diego) announced it acquired privately held Epicentre Biotechnologies (Madison, Wis.), a provider of nucleic acid sample preparation reagents and specialty enzymes used in sequencing and microarray applications, for an undisclosed price.

Illumina acquired Epicentre for access to its patented Nextera technology for next-generation sequencing library preparation, which greatly simplifies genetic analysis workflows and reduces time from sample preparation to answer.

"As next-generation sequencing continues to improve in throughput and cost, there's a critical need for sample prep to evolve as well, to lower costs, handle higher sample volumes and reduce both hands-on and overall processing time," Jay Flatley, president and CEO of Illumina, said in a statement. "Epicentre's Nextera technology provides a step-change improvement in library prep that will translate into greater ease of use, lower costs, and faster turnaround times for sequencing applications."

According to the company, researchers can use Nextera to prepare sequencing libraries from genomic DNA in less than 15 minutes of hands-on time. By comparison, standard methods for library construction can require several hours of hands-on time.

FDA Paves Way for Nanosphere, Neogen, and AdvanDx ID Tests

The U.S. Food and Drug Administration (FDA) issued 510(k) clearance for several infectious disease assays in January, paving the way for immediate test launches for Nanosphere, Neogen, and AdvanDx.

AdvanDx (Woburn, Mass.) received clearance for a test capable of identifying the most relevant pathogens for gram-negative rod (GNR) bloodstream infections. The company says its GNR Traffic Light test is the first test capable of simultaneously identifying *Escherichia coli, Klebsiella pneumonia*, and *Pseudomonas aeruginosa* directly from positive blood cultures containing gram-negative rods in less than 90 minutes, as compared to two to three days for conventional testing methods.

Early differentiation between these species can improve antibiotic therapy selection, potentially reducing cost of care in cases of hospital-acquired infections. The test, which runs on the company's PNA FISH diagnostics platform, uses fluorescently labeled peptide nucleic acid (PNA) probes that target the species-specific ribosomal RNA of *E. coli, K. pneumoniae*, and *P. aeruginosa* and displays results visually using fluorescence microscopy. The test became commercially available Feb. 1 and lists for $40 per test, according to Joen Johansen, director of marketing, for AdvanDx.

Neogen's Rapid Salmonella Test Approved for Food Safety

Neogen Corp. (Lansing, Mich.) announced that its rapid test for Salmonella enteritidis (SE) has been determined by the FDA to be equivalent to the FDA's traditional testing method in accuracy, precision, and sensitivity for detecting SE in the poultry industry.

The determination of equivalency will allow egg producers and processors to immediately use Neogen's Reveal for SE test to comply with the FDA's recently implemented SE regulations. The test's material costs are $7 to $10 per sample depending on volume.

"Until our introduction of an effective rapid test for SE, the industry had to wait up to seven days for an outside laboratory's test results," said Ed Bradley, Neogen's VP of food safety. "Reveal for SE enables the industry to get quicker results and provides the accurate answer they need to manage their flocks and egg production."

Nanosphere's Respiratory VirusTest

Nanosphere (Northbrook, Ill.) was granted 510(k) clearance for its respiratory assay, the Verigene Respiratory Virus Plus Nucleic Acid (RV+) test.

The company says that with a single test, the RV+ can detect influenza A and B and respiratory syncytial virus (RSV) A and RSV B, and can further subtype flu A as H1, H3, or 2009 H1N1.

"This timely clearance of RV+ will let Nanosphere offer customers the broadest respiratory virus panel available in the market on a sample-to-result platform," said William Moffitt, Nanosphere's president and CEO, in a statement. "Moreover, the RV+ test's clearance enables molecular respiratory testing to begin moving into mainstream medicine."

The test, which runs on the Verigene system, is operationally similar to Nanosphere's existing respiratory assay on the same Verigene system that received a CLIA categorization of "moderate complexity." The RV+ test does not contain the recommendation to confirm all negative results with culture-based detection methods.

NanoString Expands Into Molecular Diagnostics
Clinical Trials to Begin

NanoString Technologies (Seattle) is moving into the molecular diagnostics space by assembling a pipeline of proprietary, high-value content for development of in vitro diagnostic assays on its existing nCounter genetic analysis system.

The nCounter platform, launched in 2008, uses digital molecular barcoding to enable multiplexed, direct profiling of individual molecules in a single reaction without amplification. NanoString currently sells its nCounter device as a research tool to academic research groups and pharmaceutical companies but plans to modify the instrument and develop assays to reach the potentially larger diagnostic markets, including hospitals and pathology laboratories.

The Breast Cancer Intrinsic Subtyping Assay will be NanoString's first diagnostic test. Based on the PAM50 gene signature, it will measure the expression levels of these 50 genes in formalin-fixed, paraffin-embedded breast tumor tissue samples. PAM50 was created and validated by Bioclassifier, a partnership of four academic breast cancer experts in the United States and Canada. They licensed the gene signature for breast cancer to NanoString in December 2010, giving NanoString the right to develop an instrument to classify breast cancer patients into four subpopulations with varying degrees of disease severity. The company will begin clinical trials this year and hopes to receive FDA approval for the device in 2012.

The privately held company is expected to raise another round of financing in 2011 to fund its clinical trials and the regulatory submissions process.

LabCorp to Market On-Q-ity's CTC Technology

Following on the heels of last month's announced collaboration between Massachusetts General Hospital and Johnson & Johnson's Veridex, Laboratory Corporation of America and On-Q-ity will also partner to advance the use of circulating tumor cell (CTC) technology.

LabCorp (Burlington, N.C.) will market and distribute CTC technology developed by On-Q-ity (Waltham, Mass.) to its pharmaceutical research and development customers. The CTC technology is based on a microfluidic chip capable of capturing and characterizing CTCs in a blood sample, says the company. It uses DNA repair biomarkers that can be used to predict treatment response. The platform could enable the biopharma industry to accelerate the cancer drug development process by stratifying patients for selection in clinical trials and providing early indications of drug effectiveness or patient relapse. Financial terms of the deal aren't being disclosed.

"Our CTC technology can today find and characterize these elusive cells, providing a faster and more efficient way for drug developers to monitor the effectiveness of new therapies," says Mara Aspinall, CEO of On-Q-ity. "LabCorp's well-established clinical trial business will help us get On-Q-ity's groundbreaking technology into the hands of researchers as quickly as possible, ultimately changing the way cancer is treated."

While initial commercialization will occur in the research market, the company plans to enter the diagnostics market.

Qiagen Pins Future Growth on QIAsymphony RGQ System

Company Hopes for U.S. Launch in 2011, 2012

Joachim Schorr

Qiagen is a developer of products for sample and assay technologies including preanalytical preparation of biological samples, diagnostic assays, and automated instruments. The company saw 2010 revenues grow by 8 percent to $1.09 billion and is expecting revenue growth of 5 percent to 7 percent in 2011. The company is poised for growth from sales of its newly launched QIAsymphony RGQ system in Europe and continued expansion both geographically and with additions to its product lines.

Joachim Schorr, Ph.D., managing director and senior vice president of global research and development at Qiagen, spoke recently with *DTTR* about the company's pipeline of new assays in development, regulatory submissions planned for this year, and its partnerships with pharmaceutical companies for the development of companion diagnostics.

2010 Sales at a Glance

- 2010 net sales grew 8 percent to $1.09 billion
- North America accounted for 48 percent of total sales
- Consumables accounted for 85 percent of sales and instruments for 15 percent of sales

In September 2010 Qiagen launched the QIAsymphony RGQ system. How many tests are currently validated and offered on the platform and what are the plans for expanding the assay portfolio?

The QIAsymphony system is the only system that can handle any kind of biological sample and sample prep. The sample prep unit can handle blood, tissue, any body fluid, urine, anything you can think of—there are more than 100 different sample prep applications from it. So the philosophy was then to expand the capabilities of QIAsymphony SP, launched in 2007, to add an assay setup and detection module for analysis to it. We now have a complete system capable of running all different PCR-based molecular assays. We think this is a fascinating system because it gives customers in different segments the possibility to run a variety of different tests and protocols all on one platform.

There is a battery of eight different types of targets which are running on the system—the virology and transplantation panel, and we have launched HIV, HCV, and HBV to run on the system and we are currently in the process of putting the TheraScreen assays developed in conjunction with KRAS on there. Also what is planned to go on there is the influenza. It is quite extensive.

When do you expect the system to be approved for use in the United States?

We are now undergoing clinical trials to get FDA [Food and Drug Administration] approval for the transplantation piece. The plan is to submit this year, but the point is that clinical trials always have certain unpredictability . . . so the plan is to submit 501k applications and launch in late 2011 or 2012.

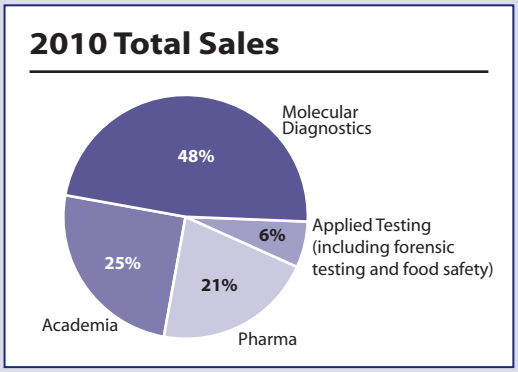
What were the key drivers for growth during 2010 and what initiatives for the coming year will drive Qiagen's growth in the future?

Growth drivers certainly are the continuous high double-digit growth which we

are seeing in personalized health care. The concept of personalized health care is not only a concept anymore but is a real business opportunity and it's a trend with all pharma companies buying into it. We have our relationships and contracts with most of the big pharma companies. We plan to get the submission for our KRAS test done in the first half of this year, which once approved will be the first PMA personalized health care product.

Another growth driver for the future, is of course, the QIAsymphony RGQ, our platform for our increasing portfolios in profiling and personalized health care. The customer feedback has been overwhelming.

Prevention is driven mainly by HPV testing. There is still a lot of ground to be taken, in the United States, but especially in Europe and Asia, which are just coming from very low rates of customers undertaking testing for HPV.



Qiagen has pursued a strategy of partnering with pharma companies to advances its position in personalized medicine. What products will we see emerging from these collaborations?

This type of business has two components. One component is the clinical research and the other is to have a lot of research activities focusing on EGFR receptor pathway and signaling cascades, which includes genes like KRAS, and all those markers have a certain relation to pharmaceuticals. We sell on the one hand kits to research customers and on the other hand we develop specialized kits for those and other markers for commercialization through pharma companies.

The interest is quite significant not only for drugs that are in late clinical development or that are already market, but now pharma is [starting] to see the benefit of using the concept early because you can increase the efficiency of clinical trial by using patient stratification. This is the exciting part of the personalized health care business.

Are most partnerships oncology-based?

Yes, currently oncology-based partnerships dominate, but we also see pharma interest in the autoimmune and cardiovascular field. The concept of personalized health care also leads to development activities in metabolic disease. There are some new partnerships which we have entered, but [about] which I cannot go into more detail.

The company hinted at "targeted acquisitions" in 2011 to 2012. Is it likely future acquisitions will also focus on molecular diagnostics and personalized medicine?

For us it is very important to continuously feed platforms with new assays. So one aspect of acquisitions is certainly to look at access to either new assays or new content we can bring on to our platform. But acquisitions are only an ingredient to our growth strategy. We constantly look at targets which help us widen our geographic reach, or provide us with access to new technologies or content. But acquisitions are not a purpose in itself. In the end they have to be accretive after 18 months and provide an excellent strategic fit for Qiagen in order to accelerate profit.

New Carrier Screening Test and Fetal Genome Discovery Could Impact Preconception, Prenatal Genetic Counseling

A new preconception carrier-screening test, described in the Jan. 12 issue of *Science Translational Medicine*, accurately identifies a couple's risk of conceiving a child with any one of 448 catastrophic childhood genetic diseases. The test, developed by the National Center for Genome Resources (NCGR; Santa Fe, N.M.), could significantly alter how preconception genetic counseling is performed.

Current carrier testing recommendations apply to only five diseases in selected populations. But the present study assessed the ability to detect mutations on 437 genes that cause 448 severe, recessive childhood diseases. The developers included severe and highly penetrant diseases on the panel for which clinical utility of testing was clear in that testing results would change family planning or affect antenatal, perinatal, or neonatal care. Milder recessive disorders such as deafness, adult-onset diseases, and conditions lacking evidence of causal mutations were omitted.

> ***"Technically we can provide much more information than we can digest. . . . But, with hundreds of diseases the whole [counseling] model has to be changed. It is not possible to talk about every disease."***
>
> ***– Callum Bell***

Using 104 unrelated DNA samples, the researchers found the average genomic carrier burden was 2.8, with a range from zero to seven. The test had 95 percent sensitivity and 100 percent specificity.

"We are at an inflection point. The practice of genetic medicine is pretty ill-equipped to deal with a test like this," says lead author Callum Bell, Ph.D., director of human genomics at NCGR and a co-developer of the test. "We expect the patient to be negative with general population screening. . . . But, with a test like ours we expect people to be positive to at least one. We are changing the expected outcome."

The test is expected to become commercially available on a research basis through a CLIA lab established at Children's Mercy Hospital (Kansas City, Mo.) in the third quarter of 2011. There are no current plans to submit the test for approval from the Food and Drug Administration. Final pricing is a "moving target," says test co-developer Stephen Kingsmore, M.D., director of the Center for Pediatric Genomic Medicine, Children's Mercy Hospital, but is expected to be less than $1 per tested condition. He expects the price to drop post-launch, while the scope of the test panel will increase. The panel currently tests for 568 diseases and could reach 750 in a couple years, Kingsmore tells *DTTR*.

While analytical costs will decrease with next-generation sequencing improvements, test interpretation, reporting, and genetic counseling will add additional costs.

"Technically we can provide much more information than we can digest," says Bell. "When we counsel a family for one disease it may take 30 minutes to one hour. But, with hundreds of diseases the whole model has to be changed. It is not possible to talk about every disease."

The authors encourage discussion of ethical, legal, and social implications of com-

prehensive carrier testing and say the discourse will influence the scope and setting of clinical adoption.

"Testing of donors for the in vitro environment is expected to happen fairly quickly and easily. Special populations will also be early adopters—testing of special populations with a family history of inherited diseases or in populations with higher rates of diseases," says Kingsmore. "Each market will be a limited launch and then we will broaden to general populations through health care providers."

Kingsmore describes the testing as "scalable," processing 192 sample batches at a time. He says the short-term goal is 20,000 tests per year in the next two to three years.

While the test developers are only interested in preconception testing, the discovery that the entire fetal genome is present in maternal plasma leads some to speculate about a broad array of noninvasive prenatal genetic testing.

Fetal Genome Discovery Could Alter Prenatal Diagnostics

Researcher Dennis Lo, FRCPS, in a proof of concept study published in the Dec. 8 issue of *Science Translational Medicine*, sequenced maternal plasma DNA and discovered the entire fetal and maternal genomes were represented in maternal plasma at a constant relative proportion of 10 percent.

> ***"The two new studies . . . expose the need for cautious application of rapidly emerging genome sequencing technologies to preconception carrier testing and prenatal genetic diagnosis."***
> ***– Laird Jackson, M.D.***

The discovery opens the door for using genome wide scanning to noninvasively diagnose fetal genetic disorders prenatally. Unlike conventional procedures, including amniocentesis and chorionic villus sampling, testing using maternal plasma DNA poses no threat to the fetus, and it could simultaneously test for multiple diseases. But it also raises ethical, legal, and social issues including how to provide genetic counseling for such a complex test and the appropriate spectrum of fetal genetic characteristics or abnormalities that can be ethically tested.

The authors speculate one direction for future development would be to apply the approach specifically to multiple disease-related genomic regions by targeted sequencing approaches, which would both reduce the cost and target counseling to a focused group of disorders.

While Lo's discovery is not immediately applicable in clinical practice, researchers acknowledge that broad access to powerful genetic tests, such as those reported in both of these recent papers, reopens public debate.

"The two new studies in *Science Translational Medicine* expose the need for cautious application of rapidly emerging genome sequencing technologies to preconception carrier testing and prenatal genetic diagnosis," wrote Laird Jackson, M.D., Drexel University College of Medicine, in an accompanying perspective piece. "Broad indiscriminate implementation of evolving genomic technologies, especially for preconception (carrier) and prenatal (fetal) testing for genetic disorders, raises concerns of unintended consequences of our technological triumphs that might undermine their purpose of improving human health."

Survey: Nurses Lack Awareness of PCT, Sepsis Testing Technology

Most critical-care nurses are unaware of the procalcitonin (PCT) diagnostic test used to identify the pathological cause of sepsis, according to a recent survey.

The survey, conducted by bioMérieux (Durham, N.C.) at the 2010 American Association of Critical-Care Nurses conference, shows that 95 percent of nurses surveyed said they assist in the management of sepsis patients but that none of their hospitals currently use PCT testing to rapidly assess suspected sepsis patients.

BioMérieux conducted the survey as a "baseline assessment" of the level of awareness of PCT as a biomarker in sepsis management.

"We know that only a minority of [U.S.] hospitals currently use PCT in their sepsis protocols," acknowledges Vince Tumminello, senior marketing manager for the Rapid VIDAS PCT test at bioMérieux Inc. "Our goal is to gain the same [strong] acceptance in the United States" as has been achieved in Germany and France where the assay was launched more than 10 years ago.

Elevated levels of the protein biomarker PCT are a telltale sign of systemic bacterial infection, as opposed to viral or fungal pathogens. BioMérieux's VIDAS BRAHMS PCT test recently received 510(k) clearance from the U.S. Food and Drug Administration to assess the patient's risk of progression to severe sepsis and septic shock. The test can distinguish the pathological cause of sepsis in 20 minutes, the company says, as opposed to two to three days using conventional blood culture methods.

The nurses reported that the primary tests ordered in their experience with the management of sepsis patients include blood cultures and lactate tests, with 83 percent acknowledging current diagnosis and confirmation testing is not fast enough.

Low β-Amyloid Levels Associated With Cognitive Decline

Plasma β-amyloid 42/40 ratio appears to be a biomarker of cognitive decline, according to a study in the Jan. 19 issue of *Journal of the American Medical Association (JAMA)*. With the number of people living with dementia expected to double in the next 20 years, identification of biomarkers that can determine an individual's risk for developing dementia or that could potentially be a target for future treatment are urgently sought.

Investigators prospectively studied 997 community-dwelling older adults from Memphis, Tenn., and Pittsburgh who were enrolled in the Health, Aging and Body Composition (Health ABC) study, which began in 1997 with 10-year follow-up. The researchers found that low β-amyloid 42/40 levels were associated with greater cognitive decline over nine years.

Older adults with low cognitive reserve (as measured by less than a high school diploma or sixth-grade or lower literacy) had an even greater association with β-amyloid 42/40 level, whereas those with high reserve had less association. Other research has shown that some individuals with extensive β-amyloid deposits, as measured by autopsy or neuroimaging, demonstrate little or no clinical symptoms of Alzheimer's disease (AD). This finding has led to a cognitive reserve hypothesis in which some

older adults with AD pathology experience fewer clinical symptoms because of compensatory factors, including higher occupational or educational achievement, greater efficiency or flexibility of neural networks, and larger brain size. The authors of this study wrote their results suggest cognitive reserve modifies the association between β-amyloid and cognitive impairment.

As a measure of genetic vulnerability, the researchers determined apolipoprotein E (APOE) e4 allele status using standard single nucleotide polymorphism techniques. Older adults with an APOE e4 allele also had a greater association with β-amyloid 42/40 level.

"The most important message from this and similar studies is that differences in proteins and peptides can be found in peripheral fluids years before clinical onset of dementia," wrote Monique Breteler, M.D., Ph.D., of Erasmus MC, University Medical Center Rotterdam, the Netherlands, in an accompanying editorial. "It is highly unlikely that within the next few decades any large population screening programs can be performed using PET imaging or other technology-intensive and invasive methods. To identify those at risk of dementia, risk factor profiles and biomarkers must be identified that can be obtained relatively easily and with minimal invasiveness."

Vermillion Receives Patent for PAD Biomarkers

The U.S. Patent and Trademark Office in January issued a patent to Vermillion Inc. (Austin, Texas) for biomarkers related to the company's VASCLIR test for the diagnosis and management of peripheral artery disease (PAD).

The patent (No. 7,867,719), titled "Beta-2 microglobulin as a biomarker for peripheral artery disease," covers both the identification and measurement of Beta-2 microglobulin and biomarker combinations by multiple methods, including mass spectrometry and immunoassay.

The VASCLIR test simultaneously evaluates various biomarkers for PAD and creates an index score to stratify an individual's risk of developing PAD. Vermillion has conducted a discovery study and a first validation study that was subsequently independently validated. Its studies have shown that patients with a high index score are seven times more likely to have PAD than patients with a low index score.

"The issuance of this PAD biomarker patent will help our efforts to develop and commercialize our VASCLIR test for PAD," said Gail Page, CEO of Vermillion. "We continue to progress our PAD program, including the initiation of our intended use study."

PAD, a blockage of the arteries of the lower extremities, is a risk factor for adverse cardiac events such as heart attack and stroke but is often underdiagnosed as symptoms are often misidentified.

PAD is currently most commonly diagnosed using the ankle-brachial index. Blood pressures are measured in the arm and at the ankles and the ratio (ankle/arm) is calculated. The company says the blood test could be more uniformly implemented and wouldn't be plagued with improper administration as is the case with conventional methods.

IVD Stocks Gain 3%; Illumina Shares Surge 12% on Strong Earnings

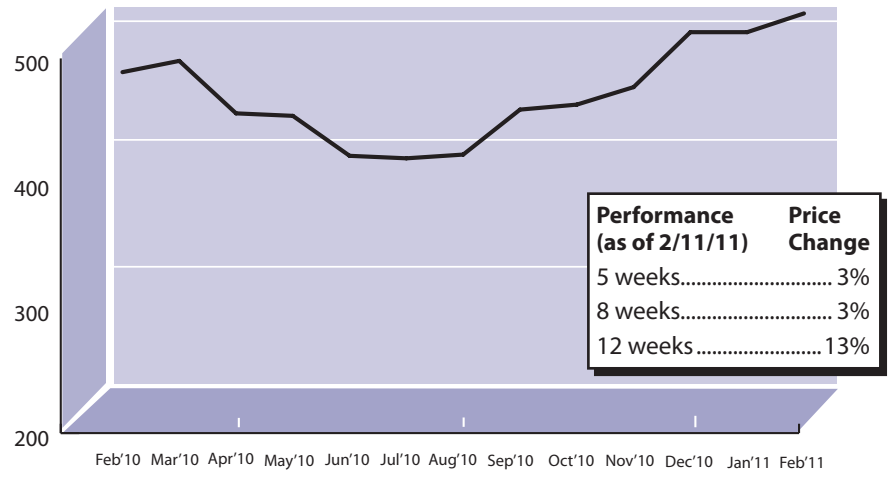
The G-2 Diagnostic Stock Index gained 3 percent in the five weeks that ended Feb. 11, with 11 stocks up in price and eight down. The G-2 Index is also up by 3 percent since January, while the Nasdaq is up 4 percent and the S&P 500 is up 5 percent over the same period.

Three companies have joined the G-2 Index for 2011: **Illumina** (San Diego), **IRIS International** (Chatsworth, Calif.), and **Qiagen** (Venlo, Netherlands). Meanwhile, Clinical Data and Nanosphere are no longer included in the index.

Gaining the most ground in recent weeks was **Illumina**. Shares in the genetic analysis instrument maker gained 12 percent to close at $73.66 per share with a market capitalization of $9.2 billion. On Feb. 8, the company announced its financial results for the fourth quarter and fiscal year of 2010. Annual revenue climbed 35 percent to $902.7 million compared to $666.3 million reported in fiscal 2009, and quarterly earnings reached $261.3 million, a 45 percent increase over the $180.6 million reported in the same period in 2009. Management attributed the revenue boost to sequencing products as well as solid year-over-year growth in Illumina's microarray business.

Also rising 12 percent during the five-week period was **Beckman Coulter** (Brea, Calif.). Shares in the diagnostics giant rose 11 percent to close at $82.78 per share. On Feb. 7, manufacturing and technology conglomerate Danaher bested bidders that included the Blackstone Group and agreed to buy Beckman for $6.8 billion, or $83.50 a share. The purchase price valued the company's equity and net debt at 8.6 times earnings before interest, taxes, depreciation, and amortization. Danaher expects to close the transaction in the first half of 2011, at which point Beckman would join the likes of Leica Microsystems, AB Sciex, and Molecular Devices in its life sciences and diagnostics unit.

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 19 IVD companies.

Up	Price	% Chg
Abaxis	$26.40	5%
Affymetrix	5.30	10
Alere	40.10	4
Beckman Coulter	82.78	11
Bio-Rad	109.19	4
Cepheid	25.01	6
Gen-Probe	63.71	9
Illumina	73.66	12
IRIS International	10.36	1
Luminex	19.42	8
OraSure	6.74	7
Down		
Abbott Labs	45.46	-5
Becton Dickinson	81.29	-2
Immucor	20.14	-4
Johnson & Johnson	62.54	-2
Meridian	22.58	-1
Qiagen	19.21	-1
Quidel	13.54	-1
Sequenom	7.00	-9

G-2 Insider

Navigating the wealth of opportunities and challenges mainstream molecular diagnostics presents . . . Once an exclusive specialty of academic medical centers and reference laboratories, molecular diagnostic testing has reached the mainstream of laboratory medicine. Join us in Boston April 13-15 for our one-of-a-kind annual conference that brings you face-to-face with the leading molecular labs, groups, and hospitals.

G-2 Reports has assembled a world-class faculty of molecular experts and laboratory business leaders from some of the nation's top labs in the areas of molecular business strategy, reimbursement, billing, legal, regulation, and results reporting—to provide you with the practical, innovative, and successful business models and strategies you need to bring your lab into the MDx mainstream.

Join us in Boston this April. Among the questions that will be examined:

- How can laboratories optimize their molecular test menus and how should they be priced?
- With increasing molecular diagnostics-based partnerships between the diagnostics and pharmaceutical industries, where do hospital labs fit in?
- How will pharmacogenomics and personalized medicine change the interaction of clinical labs and physician practices?
- What are the leading risks and challenges you should be aware of in the next two to three years in this market?
- What critical regulatory, legal, reimbursement, and coding changes are on the horizon for molecular tests?

For full program details or to register, visit *www.mdxconference.com*.

Company References

AdvanDx 781-376-0009
Beckman Coulter 714-993-5321
bioMérieux 919-620-2000
Children's Mercy Hospital 816-234-3000
Danaher 202-828-0850
Genoptix 760-268-6200
Illumina 800-809-4566
IRIS International 818-709-1244
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DTTR 3/11

 Diagnostic Testing & Technology Report (ISSN 1531-3786) is published by Washington G-2 Reports, 1 Phoenix Mill Lane, Fl. 3, Peterborough, NH 03458-1467. Tel: 973-718-4700. Fax: 973-622-0595. Web site: www.g2reports.com.

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