G2 INTELLIGENCE

# Diagnostic Testing &Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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## Gene Security Network Receives $2M NIH Grant for Prenatal Clinical Trial

Gene Security Network (GSN; Redwood City, Calif.) has received a $2 million grant from National Institutes of Health (NIH) to conduct a clinical trial to apply the company's Parental Support (PS) technology to noninvasive prenatal diagnosis. The PS technology has been used since 2008 to diagnose chromosomal and inherited genetic abnormalities from a single cell, preimplantation, during an in vitro fertilization cycle. The grant allows the technology to be tested for noninvasive prenatal diagnosis by testing the low levels of fetal DNA found in maternal blood.

"Most pregnant women undergo blood analyte screening, which results in thousands of unnecessary invasive procedures like amniocentesis and still fails to detect roughly fifteen percent of babies with Down syndrome," said Matthew Rabinowitz, Ph.D., CEO of GSN, in a statement. "In the 21st century, we should be doing much better than that. We believe GSN's Parental Support technology, when applied to a simple maternal blood draw, will substantially reduce the number of invasive prenatal procedures and undetected cases of Down Syndrome."

The prospective randomized trial will be run out of Columbia University Medical Center and is scheduled to begin later this year. For more on the future of noninvasive prenatal diagnostics, please see *Inside the Diagnostics Industry* on p. 5.

## Ovarian Cancer Screening Does Not Reduce Death in General Population

A study of nearly 80,000 women showed that screening for ovarian cancer with CA-125 and transvaginal ultrasound simultaneously did not reduce ovarian cancer mortality. The study, published in June in the *Journal of the American Medical Association* to coincide with its presentation at the American Society of Clinical Oncology 2011 Annual Meeting (Chicago; June 4-8), found that those women who were screened were also more likely to receive invasive medical procedures and associated complications as a result of being screened.

The findings are part of the Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Randomized Controlled Trial, a national trial that began in

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▲ **Ovarian Cancer Screening,** *from page 1*

1992 to determine the effect of specific cancer screening tests on cause-specific mortality. The intervention group was given annual screening with CA-125 for six years and transvaginal ultrasound for four years. The other half of the study group received usual care. Participants were followed for an average of 12 years for cancer diagnoses or death until February 2010.

The researchers found no statistically significant reduction in mortality from ovarian cancer among the women who were screened. Through the follow-up period, 212 ovarian cancer cases were diagnosed and 118 ovarian cancer deaths occurred in the intervention group as compared to 176 cases and 100 ovarian cancer deaths in the usual care group. Overall, the stage distributions were similar with stage III and IV cancers comprising more than three-quarters of cases in both groups.

"We hoped things would be better . . . but at the end, caution is certainly warranted," says Christine Berg, M.D., chief of the Early Detection Research Group at the National Cancer Institute. "I don't necessarily think that because CA-125 or transvaginal ultrasound didn't work with this approach we used, that they won't work at all. . . . We need to look at and spend considerable effort in research to understand the molecular basis of ovarian cancer better. . . . It is possible there are different biomarkers for different subtypes."

While the hope is that early detection of ovarian cancer may have the potential to improve prognosis, the researchers found that the women who were screened faced increased risk of complications resulting from often invasive procedures. Of 3,285 women with false-positive results, 1,080 underwent surgery as part of the diagnostic workup and 15 percent experienced 222 distinct, major complications (20.6 complications per 100 surgical procedures).

"I think that this provides clinicians with additional information that not screening with this approach makes sense," Berg tells *DTTR*. This does not apply to high-risk individuals, those with a family history or those women when tested that were found to have mutations like BRCA1/BRCA2. . . . Screenings should continue in those populations."

## Quest Settles Lawsuit Alleging Overcharging Medi-Cal

Quest Diagnostics (Madison, N.J.) has settled a previously disclosed lawsuit over alleged violations of the California False Claims Act involving overcharging Medi-Cal, the state's Medicaid program, for laboratory testing services for nearly a decade. This settlement is the largest recovery in the history of the California False Claims Act, according to the California Attorney General's Office.

Quest, the state's largest provider of laboratory services, agreed to pay $241 million and to follow reporting obligations in exchange for full release of all the claims alleged in the lawsuit. Instead of submitting information for the first five reporting periods, Quest has the option of submitting Medi-Cal claims at no more than 85 percent of otherwise applicable published fees for tests from May 2011 through July 2012. In an interim agreement, Quest temporarily suspended billing Medi-Cal from Sept. 1, 2010, through March 1, 2011, while continuing to provide clinical laboratory testing services.

"Our laboratory testing services for Medi-Cal were priced appropriately, and we deny all allegations in the complaint," said Michael Prevoznik, Quest's general counsel, in a statement. "California's interpretation of the Medi-Cal 'comparable charge' regulations created uncertainty and resulted in an intolerable business environment for us. . . . We also intend to pursue other avenues, including legislative action, to ensure clear regulatory standards in California for the clinical laboratory industry."

The suit was originally filed in 2005 by Hunter Laboratories against Quest and six other laboratories claiming they were unable to compete in the marketplace because of the major players' unfair billing practices. The suit alleged that Quest and the others failed to offer Medi-Cal the lowest retail price offered to other providers and that they provided illegal kickbacks in the form of steep discounts to providers in exchange for referrals. The California Attorney General's Office joined the lawsuit in 2009.

"This is a settlement, so it is not clear how a court would come out if it were to address this same issue. Nevertheless, California labs would be advised to re-evaluate pricing to avoid risk of future enforcement actions by the attorney general or other state regulators," says Esther Chang, a partner in the law firm McDermott Will & Emery in Los Angeles, which was not involved in the Quest settlement. "Because the settlement is specific to Medi-Cal . . . the concepts are limited to California. However, it is possible that other states with statutes that contain language similar to the California statutes at issue may attempt to follow this interpretation in future enforcement actions."

Similar cases are currently pending, including one against Laboratory Corporation of America (Burlington, N.C.), the state's second-largest lab services provider. That trial will begin in early 2012.

As a result of the settlement Quest updated its first-quarter 2011 results and 2011 guidance. The Medi-Cal charge reduced previously reported first-quarter income, resulting in a loss of $53 million (33 cent loss per diluted share). The company reduced its 2011 expectation of generating $1.1 billion in cash from operations to $900 million due to the charge associated with the Medi-Cal settlement.

## Human Genome Project Yields $796 Billion Economic Impact

Sequencing the human genome has empowered medical researchers and has led to diagnostics innovations that have noticeably altered laboratory testing menus. But the economic impact of the Human Genome Project (HGP) extends well beyond the diagnostics industry. A new industry report prepared by the Battelle Technology Partnership Practice (Columbus, Ohio) shows that the initial $3.8 billion federal investment in the HGP led to a $796 billion cumulative economic output.

Dubbed "the single most influential investment to have been made in modern science" the sequencing of the human genome led to the creation of an entire industry to supply the scientific research community with equipment, supplies, and services required to conduct genomics research and development (R&D) and associated product development.

The investigators examined six economic sectors to conduct the overall impact analysis including genomics-related bioinformatics, diagnostic testing, biologics substances, instruments and equipment, scientific R&D services, and drugs and pharmaceuticals. The

original 13-year investment has spurred a substantial sector that benefits the U.S. economy. In 2010 alone, genomics-associated research and industry activity generated $67 billion in U.S. economic output and $20 billion in personal income and created 310,000 jobs.

The ultimate goal of the HGP was to have a functional impact to improve our biological understanding and well-being, which the authors recognize has yet to be fully realized. Advancements resulting from DNA sequencing and other genomics technologies already stretch beyond medicine into agriculture and energy production. The economic impact of applied genomics is predicted to continue to ripple outwards.

"Its usefulness is perpetual," the authors wrote. "The reference human genome is akin to chemistry's periodic table, a perpetually useful fundamental platform for understanding and advancing science." The study was funded by Life Technologies Foundation.

## Studies Overestimate Effect Size of Biomarkers

Highly cited studies involving associations of biomarkers report bigger effect sizes than those found in larger studies or summary estimates from meta-analyses evaluating the same associations, according to a literature review in the June 1 issue of the *Journal of the American Medical Association.* The authors say their findings should reinforce "healthy skepticism" about interpreting biomarker literature emphasizing that discovering useful biomarkers is possible but that the standards for claiming success should be higher and emphasis on single studies with highly promising results may be "premature."

To understand "translational attrition," why so few of the continuously proposed biomarkers make it to clinical practice, the authors examined the accuracy of effect sizes documented in the literature. The researchers included 35 biomarker studies (published between 1991 and 2006) that had a relative risk presented in their abstract, had been evaluated in at least one highly cited study (more than 400 citations in the ISI Web of Science) published in one of 24 highly cited biomedical journals, and for which at least one meta-analysis had been performed for that same association. The highly cited biomarkers included genetic risk factors, blood proteins, other blood biomarkers, and infectious agent biomarkers. Cancer-related and cardiovascular-related outcomes predominated.

Analysis showed that 86 percent of the highly cited studies had a stronger effect estimate than the largest study. Only twice was the effect estimate stronger in the largest than in the highly cited study and in three cases the largest and highly cited study coincided. Similarly, 83 percent of the corresponding meta-analysis found a smaller effect. Only 15 associations were nominally statistically significant based on the largest studies and 32 of the 35 associations showed nominally statistically significant increased risk based on the meta-analyses.

The authors caution that given the exaggerated associations, these markers "may have no predictive ability" and "only incremental translational value for clinical use."

"If discriminating ability is overestimated, markers may become overpriced," the authors write. "Biomarkers with large populations of potential users could cause major escalation of health care costs with limited benefits. Obviously, adopting markers with no discriminating ability would be even worse. Clinical biomarker use requires robust evidence and safeguards."

# Molecular Noninvasive Prenatal Testing Market Expected to Take Off in Next Two Years

The molecular noninvasive prenatal testing market is experiencing a noticeable uptick in activity with nearly half a dozen companies set to commercially launch sequencing-based tests in the next year or two. The tests, which can detect if a fetus has Down syndrome and possibly other genetic defects from the mother's blood, are poised to transform prenatal diagnosis from invasive procedures performed on potentially high-risk patients to possibly testing all women early in pregnancy with a routine blood draw.

While there has been interest in noninvasive prenatal testing for at least 20 years, it has taken until now for the technology to advance to a point that sequencing the tiny quantities of fetal DNA present in maternal blood was even possible.

"Although the seminal discovery . . . that a baby's DNA can be detected in a mother's blood was made more than a decade ago, it has required significant advances in DNA detection and analysis methods and a huge reduction in sequencing costs to enable the development of a method that is both highly precise and cost-effective, making it suitable for routine testing and wider spread use," explains Marcy Graham, senior director of corporate communications at Sequenom (San Diego).

The advances in technology have been led by researchers from two independent laboratories—Dennis Lo, Ph.D., from the Chinese University of Hong Kong, and Stephen Quake, Ph.D., from Stanford University. Lo and colleagues published results of a validity study in January in the *British Medical Journal* showing that multiplexed massively parallel sequencing of DNA molecules in maternal plasma detected trisomy 21 (T21) fetuses 100 percent of the time with 97.9 percent specificity. Lo's patents are licensed to Sequenom. The intellectual property (IP) surrounding Quake's shotgun sequencing method for analyzing cell-free fetal DNA is licensed to microfluid chip maker Fluidigm (San Francisco), of which he is a co-founder, and to Verinata Health (San Carlos, Calif.), formerly Artemis Health.

### The Players

The companies are tight-lipped both about what aneuploidies beyond T21 will be included in their initial launched products. The tests, in various stages of development, are said to match the accuracy of karyotyping results from invasive tests like amniocentesis and chorionic villus sampling (CVS) and utilize a variety of molecular sequencing approaches, including shotgun sequencing, digital polymerase chain reaction, and selective analysis approaches like methylation markers. The proprietary analysis of the data produced by the sequencing will likely differentiate the products. Those familiar with the players in the noninvasive prenatal testing say that Sequenom is likely to be the first to market.

"Sequenom is best positioned because its IP position is locked up," says Junaid Husain, senior medical technology analyst for Ticonderoga Securities, who follows Sequenom. "The key patent, 'the 540 patent,' licensed from Dr. Lo will be a blocking patent and will create a barrier." He also cites the amount of clinical data and Sequenom's investments in expanding its infrastructure as high barriers to entry

for other companies looking to create similar diagnostic tests but does anticipate there will be lawsuits around the intellectual property at the core of noninvasive prenatal diagnostic testing.

"Sequenom's policy is to launch tests only after extensive clinical validation has been completed and published in major peer-reviewed scientific journals," Graham tells *DTTR*. "Sequenom believes it has the dominant intellectual property position and is closest to launching a fully validated test with the needed infrastructure that can meet possible high demand at launch."

Sequenom is targeting a launch date of late 2011 or early 2012 for its T21 lab-developed test (LDT) following the completion of a larger clinical validation study later this year. Testing will be performed at its CLIA-certified Sequenom Center for Molecular Medicine (CMM). The company will work with the U.S. Food and Drug Administration to obtain premarket approval and, hopefully, launch the test as an in vitro diagnostic (IVD) by 2013. While Sequenom's immediate goal is the launch of the T21 test, rarer aneuploidies, such as trisomies 13 or 18, may be added to the test over the next one to two years, says Graham.

***"Although the seminal discovery . . . that a baby's DNA can be detected in a mother's blood was made more than a decade ago, it has required significant advances in DNA detection and analysis methods and a huge reduction in sequencing costs to enable the development of a method that is both highly precise and cost-effective, making it suitable for routine testing and wider spread use."***

***– Marcy Graham, Sequenom***

Gene Security Network (GSN; Redwood City, Calif.) has taken a different route to arrive in the prenatal diagnostics market. The company has an established position in the in vitro fertilization market where it has used its Parental Support (PS) technology since 2008 to diagnose chromosomal and inherited genetic abnormalities from a single cell, preimplantation, during an in vitro fertilization cycle. The company closed a $12 million Series C financing round in November 2010 to facilitate broader application of its PS technology, which uses bioinformatics and high-throughput testing, in the reproductive market. According to Jennifer Keller, VP of marketing at GSN, the company's prospective, randomized trial will begin later this year and launch of the LDT would follow.

Verinata published results of an initial validation study in April in the journal *Clinical Chemistry*. The results show that their test, using massively parallel sequencing and a proprietary algorithm, correctly identified multiple fetal chromosomal abnormalities, including T21 and trisomy 18 (T18; Edwards syndrome). Verinata is currently conducting a prospective, blinded, clinical-validation trial with results expected later this year. The company has previously said it expects to launch its first prenatal test during the first quarter of 2012.

Meantime, LifeCodexx (Konstanz, Germany) is getting ready to unveil its first noninvasive prenatal diagnostic by the end of the year. The company concluded method development and will soon initiate a clinical validation study with at least 500 samples, says Michael Lutz, Ph.D., CEO of LifeCodexx, which is owned by GATC Biotech AG.

Tandem Diagnostics (San Jose, Calif.), has kept a lower profile than some of its competitors but is also in the midst of clinical trials for its test that employs selective analysis. The company anticipates having the results in 2012.

### The Adoption Question

"This is not like Genomic Health that needed to create a new market," says Ken Song, M.D., CEO of Tandem Diagnostics. "What differentiates prenatal testing is that it is already the standard of care. But what is currently available has some drawbacks. . . . We hope to replace it with something better."

The adoption rate will be "fairly brisk," predicts Husain. "Doctors are already very well accustomed to screening for Down syndrome." He says payers will also embrace the new technology. "Prenatal diagnosis saves the health care system and payers money, and that will be a rallying call."

"Next-generation prenatal testing is not a new line item. It is relatively cost-neutral or a slight increase," says Song. "Payers are busy. They are bombarded with claims. They [will likely] reflexively deny. But the more appeals processes that are initiated, the more painful it is to them. Once it surfaces to their radar and we get to their mind-share, I'd like to believe it will be easier [than for other new diagnostics]."

### How Big Is the Market?

- There are approximately 4 million births annually in the United States.
- Three percent to 5 percent of babies have birth defects or genetic illness.
- The high-risk market is approximately 750,000 pregnancies annually. The risk of T21 increases from one in 952 for women aged 30 to one in 30 for women over age 45.

While companies were not willing to share their anticipated pricing models, there is much speculation that the sequencing-based noninvasive prenatal diagnostic tests will be priced less expensively than the current invasive testing, which is around $1,500.

Another dynamic playing out is that the medical environment has become more consumer-centric. "Patients are very well-informed of the latest and greatest new technology and patients will find out about the new diagnostic tests out there," says Husain, and clinicians agree.

"Even if companies start marketing tests, it is unlikely everybody will jump on the bandwagon all at once … but what will happen is that well-educated, affluent women with the ability to pay will ask for the test and [at first] it will be used in a few, limited circumstances, primarily by the ability to pay," says Norton. She predicts it may take five years for widespread clinical adoption.

### The Future of Prenatal Testing

There is widespread agreement that over time there will be a shift toward noninvasive testing methods and there will be a dramatic reduction in the number of invasive procedures performed. But given the rarity of many genetic defects, ethical issues, and interpretation challenges, it is unlikely that there will ever be a single prenatal diagnostic test.

"Though this will be a significant step forward in prenatal care, there will still be a need for ultrasound and some hormone-specific testing that are able to diagnose disorders that DNA testing cannot," says Matt Rabinowitz, Ph.D., CEO of GSN. "We can also expect new high-throughput testing technologies combined with biostatistics to enable noninvasive detection of multiple chromosome disorders and de novo microdeletions, in addition to parental carrier screening for hundreds of recessive inherited diseases for which a baby could be at risk. The key will be to deliver these tests in a medically responsible manner with appropriate genetic counseling so that they make a positive impact on patient care and avoid information overload."

## Allergies and Allergy Testing Increasing; Possible Gender Difference in IgE Response

Quest Diagnostics' (Madison, N.J.) Health Trends Report, *Allergies Across America*, analyzed results of allergy testing from more than 2 million patient encounters over a four-year period and found that allergies and allergy testing are both increasing in prevalence and shifting in character. The study, the largest ever on allergy testing data, found novel gender differences in immunoglobulin (IgE) sensitization and a large shift in test ordering patterns toward primary-care physicians.

Allergy testing is an expanding business segment, Quest found. The number of patients tested for allergies increased by 19 percent, faster than general lab testing. The number of allergy tests ordered by primary-care physicians, including pediatricians, grew twice as fast as orders from allergists (49 percent increase versus 23 percent).

The analysis is based on testing results using Phadia's (Uppsala, Sweden) ImmunoCAP-specific IgE blood test on more than 14 million samples. Each test result identified sensitization to one or more of 11 common allergens (egg white, milk, peanut, soybean, wheat, common ragweed, mold, two types of house dust mites, cat skin, and dog dander). Allergen sensitization increased by 5.8 percent over the study period. Ragweed sensitization grew nationwide by 15 percent, more than any other allergen, consistent with prior climate change research. Ragweed sensitization rates were highest in the southwest, mountain, and plains states. Mold showed the second-fastest sensitization increase, 12 percent increase over the four years.

"The impact for labs is that there will be more IVD testing for IgE in clinical evaluations of patients suspected of having an allergy and that we will continue to see increased use of these assays particularly by primary-care physicians," says Stanley Naides, M.D., medical director for immunology at Quest.

Contrary to other studies, Quest found men had higher rates of sensitization to allergens than women. The researchers hypothesize that the criteria for positive specific IgE allergic response may differ between males and females and may require different reporting standards when evaluating men for allergies. In the study, sensitization rates were 10 percent higher for men than for women at all ages.

"If we need to establish different cutoffs for what is a sensitization response, the lab industry will have to work collaboratively with clinicians to establish parameters," say Naides, who says that additional research is still needed to establish if sensitization levels have different clinical significance in men.

## Charge Reminders Reduce Phlebotomy Costs, Utilization

A study published in the May issue of *Archives of Surgery* shows that phlebotomy ordering can be significantly reduced when providers know the economic cost of their ordering decisions. A weekly announcement to physicians on the amount charged to nonintensive care unit surgical patients for daily phlebotomy services reduced charges by nearly 27 percent over 11 weeks from February to May 2008.

Patients were frequently ordered unwarranted daily laboratory tests including complete blood cell counts and chemistry panels for days after their operation, even when they were recovering well, the study found. At Rhode Island Hospital surgical residents do not know the cost of ordered tests, and senior team members ordering oversight is not feasible as most are in the operating room.

The study included all nonintensive care unit patients on three general surgical services including selective postoperative patients and emergency admissions. At baseline, the charges for daily phlebotomy were $147.73 per patient per day, the average of two weeks of data. Charges for complete blood cell count and total chemistry panel were $56 and $169.09 respectively. After 11 weeks of residents being made aware of the daily charges for phlebotomy, the charges dropped as low as $108.11 per patient per day, saving $54,967 during the intervention.

Previous studies have shown computer-based interventions have been effective in changing test ordering behavior, while having no adverse effect on patient outcome including readmission rates, length of stay, or mortality.

"For the most part the house staff certainly felt sheepish because it was about them," said Elizabeth Stuebing, M.D., who conducted the study while a surgical resident at Brown University. "I received positive feedback from more senior members of the hospital staff, attending physicians, who are more judicious in their ordering behavior and see overordering as a problem of the younger generation. I'm not sure if they will pass it on to the next generation of house staff, but the subject was still on the minds of those that participated [one year later]." G2

## Thermo Fisher Tops Acquisitions With Phadia Deal

Acquisitions announced this past month continue to fit a pattern of strategic expansion of high-margin, in vitro portfolios and expansion of molecular biomarker pipelines to strategically position the acquirers for the anticipated growth of personalized medicine.

The largest deal announced was Thermo Fisher Scientific's (Waltham, Mass.) acquisition of allergy and autoimmunity diagnostics firm Phadia (Uppsala, Sweden) from the European private equity firm Cinven for $3.5 billion. The deal, which strategically expands Thermo Fisher's presence in specialty diagnostics, is expected to close in the fourth quarter of 2011 and will be funded from on-hand cash and debt.

Phadia will be part of Thermo Fisher's Specialty Diagnostics business, which has revenues of $1.4 billion. Phadia manufactures and markets complete blood-test systems to support the clinical diagnosis and monitoring of allergy and autoimmune diseases. Phadia's 2010 sales of $525 million were driven by its ImmunoCAP allergy testing products and its EliA system for autoimmunity tests.

In vitro allergy testing was an attractive, high-growth market for Thermo Fisher and is expected to grow globally by 9 percent a year. The company says there is "significant untapped potential for growth, particularly in the United States, where in vitro

testing is in the early stages of adoption, and in emerging markets, where there is low prevalence of allergy testing today." In a statement Thermo Fisher said it expects the acquisition to be immediately accretive to its adjusted earnings per share by 26 cents to 30 cents per share in 2012.

**Lab21 Acquires Fungal Diagnostics Firm**

Lab21 (Greenville, S.C.) acquired fungal molecular diagnostic firm Myconostica for an undisclosed amount at the end of May. It is the company's sixth acquisition in the past two years. Myconostica was spun out from the University of Manchester and launched three CE-marked products in Europe, Canada, and Southern Africa in 2010 that complement Lab21's infectious disease portfolio. The fungal tests detect Aspergillus in leukemia, transplant, and other corticosteroid-treated patients and Pneumocystis jiroveciiin in HIV and AIDS patients and others with suboptimal immune systems. Lab21 will launch the Myconostica fungal testing services from its new reference laboratory in South Carolina as well as its laboratory in Cambridge, U.K.

**Nestlé Acquires Prometheus Labs**

Nestlé Health Science (Lutry, Switzerland) a subsidiary of Nestlé S.A., acquired San Diego-based Prometheus Laboratories, a developer for novel pharmaceuticals and diagnostics for gastroenterology and oncology conditions including inflammatory bowel diseases like Crohn's disease and ulcerative colitis. Terms of the deal were not disclosed, but it is expected to close in the third quarter.

Nestlé Health Science became operational in January 2011 and offers nutritional solutions for people with specific dietary needs related to illnesses, disease states, or the special challenges of different life stages. The company said the acquisition will enable personalized health care solutions based on diagnostics, pharmaceuticals, and nutrition.

Prometheus reported a 26 percent increase in net sales in 2010 reaching $519 million, compared to $341.5 million in 2009. Prometheus's pipeline includes additional areas of strategic interest for Nestlé Health Science, such as metabolic conditions and brain health.

**LabCorp to Acquire Clearstone Central Labs**

Laboratory Corporation of America (LabCorp; Burlington, N.C.) has agreed to acquire Clearstone Central Laboratories (Toronto), a provider of central laboratory services for late-stage clinical trials, for an undisclosed amount. The deal, which is expected to close in the second quarter, provides LabCorp with Clearstone's global network of central laboratories and APOLLO CLPM, a proprietary clinical trials management system.

Clearstone Central Laboratories had been working with LabCorp's Esoterix division under a 2010 strategic collaboration agreement. Deutsche Bank estimates that Clearstone has annual revenues of approximately $75 million to $100 million. In a statement LabCorp said the transaction is expected to extend its global footprint in Asia Pacific and advance the company's personalized medicine strategy.

# IVD Stocks Follow Market Down, Drop 2% in Four Weeks

The G2 Diagnostic Stock Index was down 2 percent for the four weeks ending June 17, with 11 stocks down in price and eight ending the period up. The G2 Index outperformed both the Nasdaq and the S&P with the Nasdaq declining 7 percent and the S&P down 5 percent over the same period.

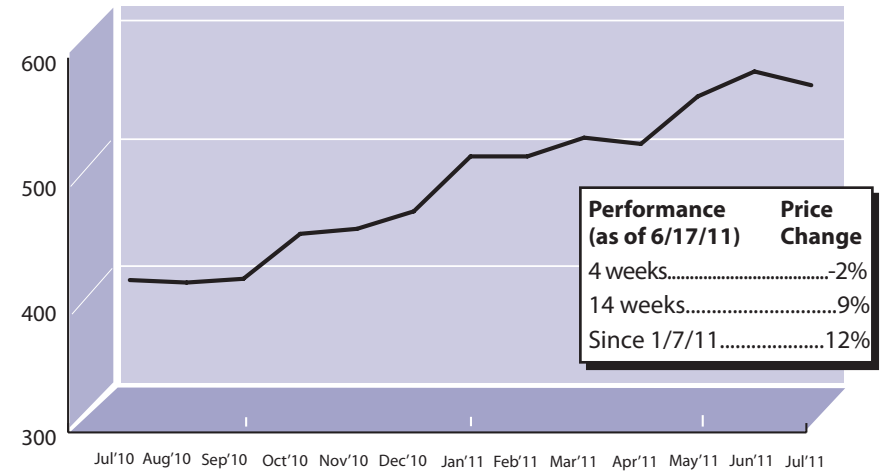
Gen-Probe (San Diego) gave back its previous period's gain of 17 percent as hype dissipated and concern rose over rumors that the pool of potential acquirers has shrunk to just one, Swiss pharmaceutical company Novartis, according to the *Wall Street Journal*. The stock reached a high of $86.66 per share on May 18 fueled by reports that Gen-Probe was up for sale. But a month later with no offers on the table the stock price sank back down to close on June 17 at $68.13 a share.

Medical and veterinary diagnostics maker Abaxis (Union City, Calif.) was down 11 percent this period despite recently launching a new veterinary rapid diagnostic test. The VetScan Giardia Rapid Test, launched in May, tests young pets for the protozoan parasite that causes gastrointestinal infections. Last month the company was also awarded $650,000 from the Kansas Bioscience Authority to help fund the first laboratory testing facility for veterinarians nationwide. The company says it is in the final stages of building in Olathe, Kan., a full-service veterinary laboratory facility focusing on esoteric testing.

The notable gainer this month was Affymetrix (Santa Clara, Calif.), up 20 percent. In mid-June the company announced HG-U133, the most widely cited gene expression microarray, is now available for use on the company's GeneAtlas personal bench-top system.

"We are unlocking important content for a whole new set of scientists who couldn't access it before," said Kevin Cannon, Ph.D., VP of marketing for expression applications at Affymetrix. The array uses more than 500,000 probes for independent measurements of gene expression per sample and nine to 11 unique probes to interrogate every mRNA transcript.

## 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 |
|---|---|---|
| Affymetrix | $7.10 | 20% |
| Beckman Coulter | 83.43 | 1 |
| Cepheid | 32.11 | 3 |
| IRIS | 9.54 | 6 |
| Johnson & Johnson | 66.29 | 1 |
| Meridian | 23.85 | 3 |
| OraSure | 8.17 | 6 |
| Quidel | 15.13 | 3 |
| **Down** | | |
| Abaxis | 27.50 | -11% |
| Abbott Labs | 51.68 | -3 |
| Alere | 35.68 | -12 |
| Becton Dickinson | 85.13 | -4 |
| Bio-Rad | 117.23 | -6 |
| Gen-Probe | 68.13 | -17 |
| Illumina | 71.42 | -2 |
| Immucor | 19.58 | -4 |
| Luminex | 18.77 | -8 |
| Qiagen | 19.10 | -5 |
| Sequenom | 7.32 | -6 |

**G2 Insider**

**Procalcitonin Testing: The Next Big Thing?** "Predicting the next big test is like gazing into a murky crystal ball—you can see some prospects, but it is not clear which tests will break out and become the next big thing," says William Schreiber, M.D., a consultant pathologist at Vancouver General Hospital and a board member at the American Society for Clinical Pathology. But he says to keep an eye on procalcitonin testing, which has the potential to become much more common than it is currently.

Procalcitonin testing is much more widely used in Europe, but doctors in the United States are starting to take notice. Procalcitonin testing can assess the risk of sepsis in critically ill patients as well as assist in more appropriately directing antibiotic therapy.

Procalcitonin is a precursor to the thyroid hormone calcitonin and is normally present in low levels in the blood. However, when stimulated by an intense stressor, like a systemic bacterial infection or other infections caused by tissue damage from trauma, surgery, heart attack, or organ transplant rejection, it may also be made by other cells in the body, causing an elevated level.

A procalicitonin test can differentiate from sepsis or viral infection, which may present with similar symptoms. Low concentrations (below 0.5 ng/mL) almost rule out severe sepsis or septic shock and may indicate a localized infection, a systemic infection that is less than six hours old, or that the person's symptoms are likely due to another cause. High levels of procalcitonin (above 2 ng/mL) indicate a high probability of sepsis and suggest a higher risk of progression to severe sepsis and then to septic shock. By separating patients with bacterial rather than viral infections, the procalictonin test can assist in curtailing unnecessary antibiotic treatment. The BRAHMS (Berlin, Germany) PCT test is approved by the U.S. Food and Drug Administration and is marketed by bioMérieux (Marcy l'Etoile, France). G2

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Early Detection Research Group, NCI 301-496-8544
Gene Security Network 650-249-9090
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LabCorp 336-229-1127
LifeCodexx +49 (0) 7531-81 60 15
McDermott Will & Emery 310-277-4110
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Thermo Fisher Scientific 781-622-1000
Ticonderoga Securities 617-757-7880
Vancouver General Hospital 604-875-4111
Verinata Health 650-632-1680







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