Diagnostic Testing and Technology Report

Competitive Intelligence & Analysis for an Expanding Global Market

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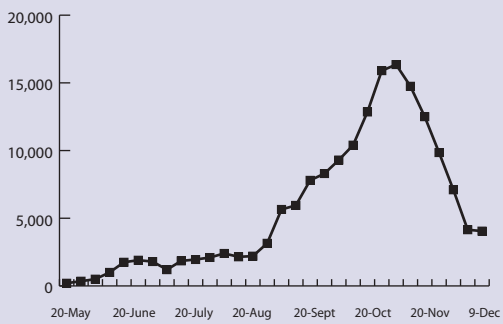
H1N1 Flu Testing Volume Down 75% Since October

Influenza activity across the United States decreased sharply in November and December, according to surveillance data from the Centers for Disease Control and Prevention (CDC). During the week of Dec. 6, 7 percent of specimens tested by U.S. World Health Organization and National Respiratory and Enteric Virus Surveillance System collaborating laboratories and reported to CDC were positive for influenza. However, the 2009 influenza A (H1N1) virus remains dominant. More than 99 percent of all subtyped influenza A viruses reported to the CDC in that period were 2009 influenza A (H1N1) viruses.

2009 H1N1 Test Volume by Week



Source: Quest Diagnostics

At Quest Diagnostics (Madison, N.J.), H1N1 testing volume declined by 75 percent between the peak week of Oct. 22-28 and the week of Dec. 3-9, when it returned to August levels. Quest also reported decreased positivity rates. About half of the 170,000 patient samples processed by the laboratory company between May 11 and Dec. 9 tested positive for H1N1. In November, that proportion dropped to 44 percent and for the two weeks ending Dec. 9, only 21 percent of specimens tested positive. For more on H1N1 flu trends, see *Inside the Diagnostics Industry*, p. 5.

Becton Dickinson Completes $275 Million Acquisition of HandyLab

Becton, Dickinson, and Co. (BD; Franklin Lakes, N.J.) is looking to boost its footprint in the molecular diagnostics market. The company has paid $275 million for HandyLab (Ann Arbor, Mich.), a developer and manufacturer of molecular diagnostic assays and automated platforms.

In May 2009, BD and HandyLab announced plans to develop and commercialize molecular tests on HandyLab's automated Jaguar platform. The bench-top system is designed to accommodate batch workflows as well as on-demand testing. BD now plans to migrate its BD GeneOhm molecular assays for methicillin-resistant *Staphylococcus aureus*, *Clostridium difficile*, and vancomycin-resistant Enterococcus onto the Jaguar platform, which will be marketed under the name BD MAX.

Continued on p. 2

▲ **Becton Dickinson,** *from page 1*

According to Philippe Jacon, president of BD Diagnostics's Diagnostic Systems division, the company's ultimate goal is to broaden its molecular test menu, beginning with health care-associated infections. Among the features of HandyLab's original Jaguar platform was an open menu, allowing for the integration of laboratory-developed tests. BD's latest molecular diagnostics deal, announced in October 2009, came weeks after Gen-Probe (San Diego) agreed to acquire molecular diagnostics company Prodesse (Waukesha, Wis.), which operates both a CLIA-certified reference laboratory and a manufacturing facility that makes its test kits and reagents available to other laboratories.

deCODE Genetics Files for Bankruptcy

After exploring various restructuring schemes that ultimately proved untenable, deCODE Genetics (Reykjavik, Iceland) filed for Chapter 11 with the U.S. Bankruptcy Court for the District of Delaware. The genetic analysis company, which operates a CLIA- and CAP-certified laboratory, is seeking to sell off its assets.

Concurrent with its Chapter 11 petition, deCODE agreed to sell its Iceland-based subsidiary Islensk Erfdagreining (IE) and its drug discovery and development programs to Saga Investments for an undisclosed amount. IE conducts deCODE's human genetics research; manages its population genetics resources; and provides its personal genome scans, DNA-based risk assessment tests, and genomics services for contract customers. deCODE recently sold its U.S.-based subsidiaries deCODE Biostructures and Emerald BioSystems.

On Nov. 24, the Bankruptcy Court granted deCODE permission to continue operating its business during the Chapter 11 proceedings. The orders included interim court approval of financing from Saga Investments that will be used to support deCODE and its Icelandic subsidiary's operations, products, and services through the conclusion of the court-supervised sale process.

Meanwhile, deCODE researchers published a notable study in the Dec. 17 issue of *Nature* detailing the discovery of a single nucleotide polymorphism (SNP) linked to type 2 diabetes. Strikingly, the effect of the SNP, which is located on chromosome 11, depends on the parent from which it is inherited. When inherited from one's father, the variant increases risk of type 2 diabetes by more than 30 percent compared to those who inherit the non-disease-linked version, but if inherited maternally, the variant lowers risk by more than 10 percent.

This research, carried out using deCODE's unique populationwide genealogy database and statistical tools, will likely be used to enrich deCODE T2, the company's three-year-old molecular diagnostic test for type 2 diabetes. Offered through the company's reference laboratory, the test detects disease-linked SNPs in the TCF7L2 gene that were discovered by deCODE researchers in 2006.

FDA Authorizes Emergency Use of H1N1 Flu Tests from Roche, DxNA, TessArae

Steep declines in testing for 2009 H1N1 influenza A virus have not slowed the progress of the U.S. Food and Drug Administration (FDA) in expanding

Agency's latest EUAs include point-of-care and microarray-based tests for 2009 H1N1 influenza A virus.

testing options for clinical laboratories nationwide. The agency recently added molecular diagnostic tests manufactured by Roche (Basel, Switzerland), DxNA (St. George, Utah), and TessArae (Potomac Falls, Va.) to its growing list of assays that can be used to detect 2009 H1N1 influenza infection under emergency use authorization (EUA).

Use of the tests, which remain uncleared by the agency, is authorized only for the duration of the declaration of 2009 H1N1 influenza virus as a public health emergency, which is currently set to expire on April 26, 2010.

On Nov. 16, the FDA granted an EUA for Roche's RealTime ready influenza A/H1N1 detection set, which runs on Roche's Lightcycler system. The test kit uses real-time polymerase chain reaction (PCR) to detect RNA from the 2009 H1N1 influenza A virus. Roche made the test available for life science research in May 2009.

Also newly authorized for emergency use is the 2009 H1N1 influenza virus diagnostic test that runs on DxNA's GeneSTAT platform, a new PCR-based system that consists of a portable analyzer that can be used at the point of care. The test detects the virus from nose swabs.

Finally, in late December, the FDA authorized emergency use of the first microarray-based H1N1 flu test. Developed by TessArae using Affymetrix technology, the TessArray resequencing influenza A microarray detection panel (TessArray RM-Flu test) is a targeted sequencing assay. It is aided by an algorithm that relies on seasonal A/H1N1 and seasonal A/H3N2 influenza virus results. The test, which uses throat swab samples, is authorized for use by CLIA high-complexity laboratories that have access to Affymetrix microarray instrumentation.

The FDA has already granted EUAs to H1N1 flu tests manufactured by Diatherix Laboratories (Huntsville, Ala.), Prodesse (now part of Gen-Probe), and Focus Diagnostics, the infectious disease diagnostics business of Quest Diagnostics (Madison, N.J.). Focus's real-time reverse transcription polymerase chain reaction (rRT-PCR) diagnostic test was the first commercial H1N1 test to be granted an EUA. The FDA had previously granted the Centers for Disease Control and Prevention two EUAs for diagnostic tests.

Gen-Probe Receives FDA Clearance for Prodesse Parainfluenza Test

Gen-Probe (San Diego), which in October 2009 completed its $60 million acquisition of Prodesse, has received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) to market Prodesse's molecular test for the detection and differentiation of parainfluenza 1, 2, and 3 viruses, which cause lower respiratory tract infections.

The ProParaflu+ assay uses real-time reverse transcriptase polymerase chain reaction (RT-PCR) to identify the parainfluenza 1, 2, and 3 viruses from nasal swabs. Because the assay uses the same internal control as Prodesse's other tests for respiratory viruses, a single nucleic acid extract can be tested with any combination of these products.

The ProParaflu+ assay joins Prodesse's FDA-cleared tests for the detection and differentiation of influenza A virus, influenza B virus, and respiratory syncytial virus, and a test to detect human metapneumovirus.

In October 2009, the FDA granted an emergency use authorization for the Prodesse ProFlu-ST influenza A subtyping assay. The test is to be used for the diagnosis of 2009 H1N1 influenza virus infection provided that it is aided by an algorithm that relies on seasonal influenza A/H1 virus and seasonal influenza A/H3 virus results in individuals who are diagnosed with influenza A by currently available FDA-cleared or authorized devices.

At Gen-Probe's annual analyst meeting, held Dec. 3 in New York City, Senior Vice President Eric Tardif discussed the company's strategic rationale for acquiring Prodesse, which he described as "a platform-independent, content-focused business" in the area of real-time PCR. "What this [acquisition] did was it allowed us to quickly get some additional assays into the marketplace, calling on our existing customers, without the need to develop our own box . . . or place additional boxes."

Prodesse saw robust growth in 2009, taking market share from culture and direct fluorescent antibody testing as well as other molecular tests and rapid assays, according to Tardif. Looking ahead to 2010, Gen-Probe expects that the Prodesse business will contribute $15 million in revenue.

Gen-Probe plans to maintain Prodesse's facilities in Waukesha, Wis. In terms of assay development, the goal is continue focusing on developing infectious disease tests for existing platforms, predominantly in the respiratory category. "Other areas of interest will also align with where Gen-Probe is going more broadly," said Tardif, pointing to women's health and hospital-acquired infections.

Medicare Finalizes Decision to Cover HIV Screening

An estimated 1.1 million Americans are infected with HIV.

The Centers for Medicare and Medicaid Services (CMS) has finalized its decision to expand the Medicare preventive services benefit by adding coverage of voluntary HIV screening for beneficiaries, effective immediately. The agency announced earlier this year that it was considering this step.

In a final coverage decision memo released Dec. 8, CMS said, "The evidence is adequate to conclude that screening for HIV infection, which is recommended with a grade of A by the U.S. Preventive Services Task Force (USPSTF) for certain individuals, is reasonable and necessary for early detection of HIV."

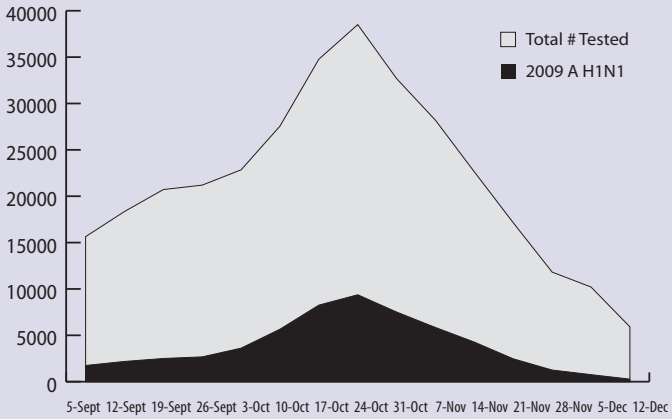
CMS will cover HIV screening with an FDA-approved enzyme immunoassay (EIA), enzyme-linked immunosorbent assay (ELISA), or rapid HIV antibody test for Medicare beneficiaries at increased risk for HIV infection under USPSTF guidelines. The covered population includes people who request an HIV test but report no risk factors, "since this group is likely to include individuals not willing to disclose high-risk behaviors." The decision also covers HIV screening of pregnant Medicare beneficiaries.

Medicare coverage of HIV screening marks the first time CMS has exercised its new authority to expand the Part B benefit without first obtaining congressional approval. CMS has had this power since Jan. 1, 2009, provided that certain conditions are met, under provisions of the Medicare Improvements for Patients and Providers Act of 2008.

H1N1 Virus Activity and Testing Volumes Down From Fall High, but Labs Remain Vigilant

As influenza activity declined in November and through the middle of December, clinical laboratories across the country reported sharp drops in flu testing volumes. The U.S. World Health Organization (WHO) and National Respiratory and Enteric Virus Surveillance System (NREVSS), which collect and monitor flu testing data submitted by laboratories located in all 50 states and Washington, D.C., reported total flu test volume of 5,640 for the week ended Dec. 12, down 81 percent from the high of 29,131 samples tested during the week ended Oct. 24.

Influenza Viruses Isolated by WHO/ NREVSS Collaborating Laboratories 2009*



Source: CDC
*Total virus number includes isolated influenza A viruses that were not subtyped as well as viruses identified as influenza A(H1), A(H3), and B.

The flu testing volume trends reported to the Centers for Disease Control and Prevention (CDC) by WHO/NREVSS collaborating laboratories is comparable to that observed by Quest Diagnostics (Madison, N.J.), which reported a 75 percent drop in its 2009 H1N1 influenza testing rates between late October and early December.

Looking closer at the testing data reveals that while H1N1 remains dominant (accounting for 99 percent of all subtyped influenza A viruses reported to the CDC during the second week of December), positivity rates have declined along with volume. The lab data reported to CDC indicates that by mid-December, 7 percent of all samples submitted for flu testing tested positive for some form of the virus, including A(H1), A(H3), and B as well as H1N1 and influenza A that could not be subtyped. Only 5 percent were identified as H1N1. This is a striking change from earlier this fall, when 39 percent of samples were testing positive for flu and 32 percent for H1N1.

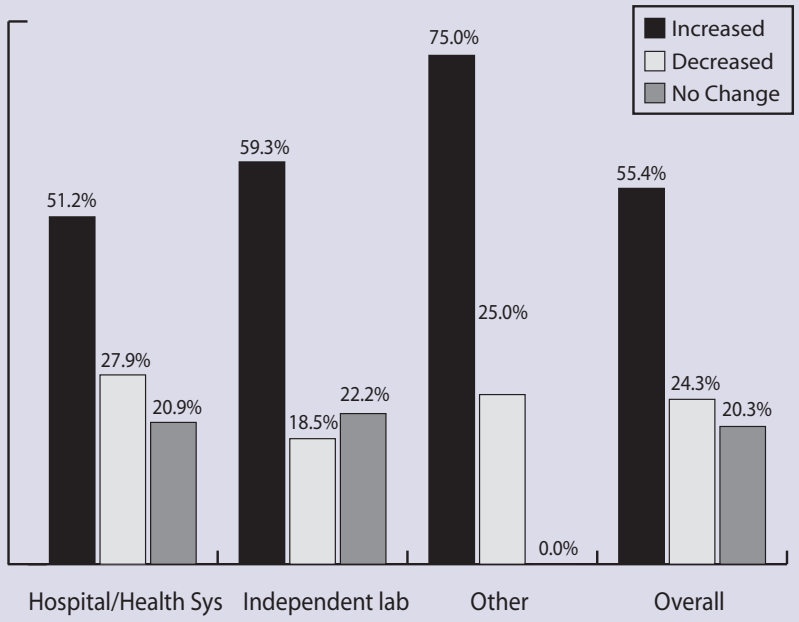
Data from Quest also shows a decline in positivity rates. For the first two weeks of December, 21 percent of samples tested by Quest for H1N1 were positive, compared to approximately 50 percent at the late October peak. From a regional perspective, the number of positive test results has dropped nationwide, reports Quest, with the most striking decline in positive test results occurred in the region comprised of Pennsylvania, Maryland, Delaware, the District of Columbia, Virginia, and West Virginia. Testing rates in that region fell 87 percent during the two weeks ended Dec. 9 compared to the prior two-week period.

Quest has described the recent H1N1 trends as indicative of the end of a "second wave" of the virus, which was first identified in late April 2009. Given the severity of the current flu season and the fact that flu tends to peak between December and February, many are wondering whether a third wave is around the corner. "Flu season generally lasts until May, and when we've asked flu experts from around the country and around the world what they think will happen in the rest of this flu season, about half think we'll have a lot more cases between now and May. And about half think we won't," said CDC Director Thomas Frieden, M.D., during a Dec. 10 press briefing. "The truth is we don't know. Only time will tell."

Lab Test Volumes Climb in 2009, G-2 Survey Finds

As the U.S. economy struggled to climb out of the recession during the second half of 2009, 55.4 percent of laboratories surveyed by Washington G-2 Reports indicated that their test volumes increased during the second and third quarters. These results are among the latest findings in G-2's ongoing Lab Test Volume and Revenue Survey, which is focused on assessing the impact of the economy on the lab industry.

Laboratory Test Volume Trends (April - August 2009)



Source: Washington G-2 Reports Lab Test Volume and Revenue Survey 2009.
Note: "Other" includes pathology groups and public health laboratories, among other labs.

For the full year 2009, a majority of the labs surveyed—62.2 percent—expected an increase in testing volumes and an estimated 8.9 percent change compared to the full year 2008. In contrast, 23 percent are expecting a decrease and 14.9 percent are predicting no change in test volumes. When analyzed by lab type, 53.5 percent of hospital/health system labs, 74.1 percent of independent labs, and 75 percent of other labs forecasted a volume increase for full-year 2009. The respondents' average overall total test volume for 2008 was 4.9 million; the median was 1 million.

As the economy improves, more respondents reported that they are beginning to ease up on cutbacks made over the past two years. When asked about what actions the lab is taking in response to indications of economic recovery, 42.9 percent said they had increased (or unfrozen) equipment, reagent, and supplies purchases; 25.4 percent said they had increased staffing head counts; 22.2 percent said that holds on salary increases had been released; and 22.2 percent said that they had changed the test mix. Other answers included price adjustments (15.9 percent) and removal of restrictions on travel, training, and other human resources costs (12.7 percent).

However, belt-tightening measures remain in effect for some labs. Some noted that things are still tight, cost-containment measures are still in place, and that reduction efforts would continue on throughout 2010. "We are not seeing any recovery as far as increased volumes," wrote one respondent. "I have done an across-the-board staffing hours reduction of 30 minutes per workday."

Looking ahead to volume growth by testing category in 2010, the overall responses seem to indicate that anatomic pathology (AP) and "other" testing—including molecular testing and clinical pathology—will be the areas where labs will experience the most volume growth. Respondents noted that they are forecasting 11.6 percent volume growth in other testing, 8.3 percent in AP testing, and

6.9 percent growth in esoteric testing. However, some might view AP volume growth as soft. Respondents that are expecting a drop in AP volumes estimated that decrease at 7.5 percent.

When asked about new avenues of growth for labs in 2010, 61.2 percent pointed to expansion into new geographic areas, 59.7 percent highlighted the introduction of more high-end tests, 31.3 percent said enter into joint venture arrangements, and 4.5 percent said acquire other labs. In the "other" category, which received 22.4 percent of responses, write-in responses included open more draw sites in service areas, increase sales efforts, grow outreach operation, work to acquire higher percentage of the business from current clients, and incorporate associated lab testing from new medical groups. Nevertheless, some are unconvinced that the worst is over. "I just don't agree the recession is over or that the recovery is beginning," noted one respondent to this question.

Cystic Fibrosis Screening Linked to Decreased Disease Incidence

Carrier screening for cystic fibrosis (CF) was associated with decreased incidence of the disease in northeastern Italy, according to the results of a study published in the Dec. 16 issue of the *Journal of the American Medical Association* (*JAMA*).

CF is an autosomal recessive disease that results from mutations in the CF transmembrane regulator (CFTR) gene. The chronic pulmonary disease has an incidence of one in 3,300 and is most common in Caucasians.

Aided by the proliferation of affordable and rapid molecular testing platforms, laboratory testing and carrier screening for CF is now widespread. However, whether this testing has affected incidence of the disease has proved difficult to assess. Several studies of trends in the incidence of newborns with CF have given contradictory results, with some studies suggesting a progressive decrease in the incidence of newborns with CF in some areas.

A research team led by Carlo Castellani, M.D., of the Cystic Fibrosis Center at Verona Hospital (Verona, Italy) evaluated the association between CF carrier screening and CF birth incidence in northeastern Italy, where neonatal screening for CF has been performed for many years. Since the early 1990s, the area has seen a significant progressive decrease of CF birth rates.

CF carrier screening in the area studied differs by region. In the western region, CF carrier tests are offered only to relatives of patients or to couples planning in vitro fertilization, while in the eastern region, carrier testing is offered to relatives and carrier screening to infertile couples and to couples of reproductive age.

Of the 779,631 newborns that underwent CF neonatal screening during the study period (1993-2007), 195 had CF detected. Over the 14 years studied, a time-related decrease in CF birth incidence was found, with an average annual percentage decrease of 0.16 per 10,000 neonates. The rate of decrease was greater in the eastern region (0.24 per 10,000) than the western region (0.04 per 10,000).

The researchers linked the eastern region's significant decrease in CF birth incidence to its intensive screening of couples of reproductive age, compared with the more limited approach used in the western region. "The overall negative

trend in northeastern Italy is mainly due to a reduction of CF births in the eastern region," concluded the authors. "The reduction appears to be connected with the extensive use of mutation analysis in the general population—as the number of individuals screened with the CF carrier test progressively increased, CF birth incidence gradually and constantly decreased."

Life Technologies Completes Purchase of BioTrove

On Dec. 15, Life Technologies (Carlsbad, Calif.) completed its acquisition of privately held BioTrove (Woburn, Mass.), maker of the OpenArray platform for gene expression analysis. Financial terms of the deal were not disclosed.

Life Technologies, formed in 2008 as a roll-up of Invitrogen and Applied Biosystems, plans to integrate the OpenArray platform into its Applied Biosystem offerings, namely its TaqMan assay family, which includes assays for gene expression and genotyping applications.

The Life Technologies deal excludes BioTrove's RapidFire division, which develops drug-discovery technologies using in vitro assays. This division will be spun out and operated independently of Life Technologies under the name Biocius Life Sciences.

Clarient Acquires Applied Genomics

On Dec. 21, cancer testing laboratory Clarient (Aliso Viejo, Calif.) announced its acquisition of Applied Genomics (AGI; Huntsville, Ala.) in an all-stock merger valued at up to $17.6 million. Privately held AGI mines gene expression data to develop novel cancer tests. The company also operates its own CLIA laboratory, where it performs its commercially available immunohistochemistry assays designed to aid in the diagnosis of non-small cell lung cancer (Pulmotype) and prognosis of breast cancer (Mammostrat).

According to Clarient CEO Ron Andrews, AGI will significantly enhance the company's pipeline of proprietary cancer tests. A nationwide launch of Pulmotype is planned for the first quarter of 2010. The five-antibody test can be used to aid in the histological distinction between adenocarcinoma and squamous cell carcinoma in non-small cell lung cancer tumor specimens.

"Having a test that provides us access to the primary lung tumor block much earlier in the diagnostic process will allow Clarient to provide pathologists with critical information at the early stages of therapy decision," noted Andrews, who added that AGI could also boost Clarient's share of the growing market for epidermal growth factor receptor (EGFR) mutation testing. "The development of lung cancer diagnostics has been slow relative to other cancers; however, we now have a powerful foundation upon which to build a market-leading lung cancer franchise."

AGI's pipeline includes cancer diagnostic, prognostic, and theranostic tests at various stages of validation and planned commercialization. Among them is a theranostic test that may predict the response of a patient's cancer to taxane, a widely used chemotherapy, across a variety of cancers. Clarient also indicated that it will consider integrating AGI's breast cancer markers into a future version of its recently launched Insight Dx test.

Screening Test Can Identify Newborns With Blood Disorder, *JAMA* Study Finds

Researchers demonstrate that a relatively low-cost molecular test can identify infants with primary and secondary forms of T-cell lymphopenia.

The testing of DNA from a statewide blood screening program for newborns in Wisconsin was able to identify infants with T-cell lymphopenia, a blood disorder that affects the child's immune system, according to a study published in the Dec. 9 issue of the *Journal of the American Medical Association* (*JAMA*).

Infants with severe T-cell lymphopenia (abnormally low level of white blood cells), including severe combined immunodeficiency (SCID), often appear normal at birth and have no family history of immunodeficiency. "Consequently, many infants with severe T-cell deficiencies are not identified until life-threatening infections occur," note the authors. "This is an important issue because the long-term prognosis of infants with SCID and other serious immunodeficiencies is markedly improved if the diagnosis is made early, before the onset of serious infections." They add that some vaccines that are recommended in early infancy can cause serious infection in infants with T-cell lymphopenia. This could be avoided with early detection.

A research team led by John M. Routes, M.D., of the Medical College of Wisconsin and Children's Research Institute (Milwaukee) conducted a study to examine if determining the number of T-cell receptor excision circles (TRECs) using DNA extracted from dried blood spots on newborn blood screening (NBS) cards could detect T-cell lymphopenia in newborn infants in a statewide screening program.

Throughout 2008, the Wisconsin State Laboratory of Hygiene screened all infants born in Wisconsin for T-cell lymphopenia by quantitating the number of TRECs contained in a portion of the NBS card. T-cell lymphopenia was confirmed by further testing.

During the yearlong study period, 71,000 infants were screened by the TREC assay. Seventeen infants had at least one abnormal TREC assay, 11 of whom had samples analyzed to enumerate T cells. Eight infants demonstrated T-cell lymphopenia and were then evaluated by a clinical immunologist.

The researchers suggest that these results support inclusion of T-cell lymphopenia in state newborn screening programs. The incidence of primary and secondary immunodeficiencies identified by the TREC assay were found to exceed the required incidence of disease to institute screening, and the TREC assay is relatively inexpensive (approximately $5.50 per assay).

"Based on an analysis of potential cost-effectiveness of NBS for SCID, the relatively high incidence of T-cell lymphopenia and the low cost of the TREC assay suggest NBS may be cost-effective as well, although a formal cost-effectiveness analysis is needed," note the authors. "In conclusion, the Wisconsin screening program demonstrates the feasibility of the TREC assay performed on NBS cards to identify infants with primary and secondary forms of T-cell lymphopenia."

Genetic Findings May Translate to New Test for Lung Cancer

Newly identified immune system markers in the blood indicate early-stage lung tumors in people at high risk for developing lung cancer. The findings, published online Dec. 1 in *Cancer Research*, could lead to a simple blood test that can detect lung cancer in its earliest phases.

Researchers examined gene expression profiles in blood samples from more than 200 patients with lung cancer or other, nonmalignant, lung diseases. Focusing on non-small cell lung cancer (NSCLC), and the at-risk population of smokers and ex-smokers, the researchers sought to determine whether lung tumors—even at the earliest stages—leave a gene expression signature in circulating blood cells.

Early diagnosis followed by surgery presently is the most effective treatment for NSCLC, which accounts for 75 percent of lung tumors.

The team was able to identify a 29-gene "signature" that separated patients with NSCLC tumors from patient controls with nonmalignant lung conditions. Immune cells showed certain changes in the patients with malignant tumors that distinguished them from those of patients with other lung diseases. The tumor gene signature was also found to decrease or disappear in NSCLC patients who had their tumors surgically removed.

The findings may serve as the basis for developing a simpler screening test for lung cancer. "Such a test could be especially useful for remote areas where typically technologies that are used in urban centers are not available," said senior author Louise C. Showe, Ph.D., a professor at the Wistar Institute (Philadelphia). "In addition, this test could be useful in a clinical setting to help to decide whether a small tumor detected on an X-ray is likely to be malignant."

BD Receives Expanded Clearance for STD Tests

BD Diagnostics, a segment of Becton, Dickinson, and Co. (Franklin Lakes, N.J.), has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to utilize two of its amplified DNA assays for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* with samples collected during routine liquid-based Pap testing for cervical cancer screening.

The assays are indicated for use with asymptomatic and symptomatic individuals to aid in the diagnosis of chlamydial and gonococcal urogenital disease, the two most common sexually transmitted diseases. The World Health Organization estimates that 92 million new cases of chlamydia and 62 million new cases of gonorrhea are diagnosed each year.

The BD ProbeTec Qx amplified DNA assays are the first to receive FDA clearance for gynecological specimens collected and transported in liquid-based cytology preservative media. The qualitative assays, which are run on BD's fully automated Viper platform, were initially cleared by the FDA in March 2009 for use with clinician-collected female endocervical and male urethral swab specimens, patient-collected vaginal swab specimens, and male and female urine specimens.

IVD Stocks Gain 6%; OraSure Up 20% on Medicare Decision to Cover HIV Testing

As of Dec. 11, the G-2 Diagnostic Stock Index reached its highest level since September 2008, having gained an average of 3 percent in the preceding five weeks, with 11 stocks up in price, four down, and one unchanged. The G-2 index is up by a third (33 percent) since January, while the Nasdaq has gained 39 percent and the S&P is up 24 percent over the same period.

OraSure (Bethlehem, Pa.) climbed 20 percent to close at $4.19 per share and a market capitalization of $219 million. Shares in the test maker got a boost from news that Medicare will now pay for HIV testing. Announced on Dec. 8, the coverage decision affects Medicare beneficiaries who are at increased risk for HIV, including pregnant women. However, CMS has indicated that Medicare participants of any age who voluntarily request the service will also be covered.

Abbott Laboratories (Abbott Park, Ill.) also saw a gain in recent weeks. Shares in the medical technology company were up 4 percent to close at $53.77 with a market capitalization of $83.3 billion. The company recently agreed to acquire Starlims (Tel Aviv, Israel), a provider of laboratory information management systems, for $123 million. Abbott hopes the deal will boost its presence in healthcare informatics as the area becoming increasingly important to laboratories as a way to automate the retrieval, communication, and management of data and aid compliance with regulatory and industry standards.

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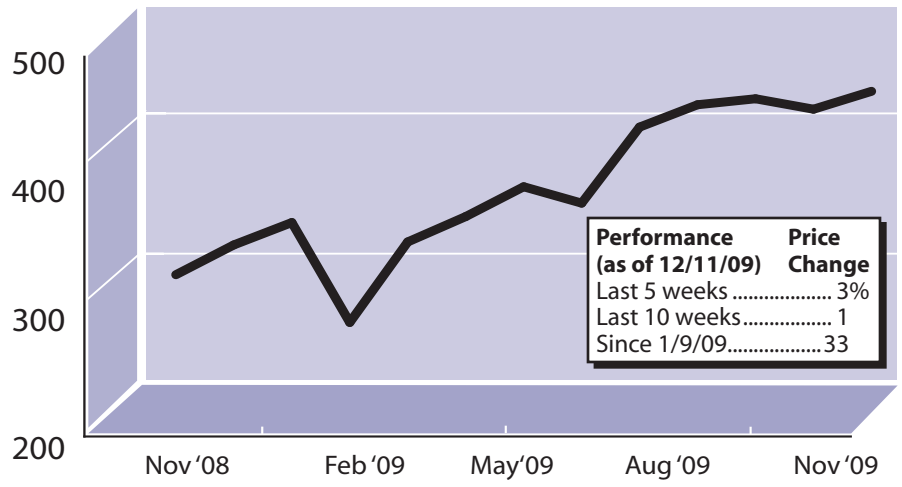
The poorest performing stock in recent weeks was **Quidel** (San Diego), which slipped 13 percent. The maker of point-of-care tests ended the period with a share price of $12.99 and a market capitalization of $403 million. As fears of novel H1N1 flu have subsided, so did the strength behind the flu test maker's performance for most of 2009. In late November, Quidel fell below its 200-day moving average. The company recently extended its common stock repurchase program to authorize the repurchase of up to an additional $25 million in shares.

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 16 IVD companies.

Up	Price	% Chg
Abaxis	$23.25	1%
Abbott Labs	53.77	4
Beckman Coulter	67.36	3
Becton Dickinson	77.45	10
Clinical Data	17.25	13
Gen-Probe	42.59	4
Immucor	19.58	6
Inverness Medical	41.73	5
Johnson & Johnson	64.85	8
Luminex	14.44	2
OraSure	4.19	20
Unchanged		
Bio-Rad	97.07	0
Down		
Affymetrix	5.55	-3
Meridian	21.38	-6
Nanosphere	6.37	-6
Quidel	12.99	-13

G-2 Insider

CLIA Lab Exits and Entries. . . . With the U.S. Food and Drug Administration (FDA) increasing its scrutiny of laboratory-developed tests (LDTs) performed in CLIA-certified laboratories, in vitro diagnostic companies are increasingly re-evaluating the so-called "CLIA lab model."

Exiqon (Vedbaek, Denmark), which operates both life sciences and diagnostics divisions, announced on Dec. 17 that it is divesting Oncotech, the California-based CLIA laboratory operation it acquired in 2007. The company described the decision as part of a move "to gain operational and infrastructural efficiencies and to free up human and financial resources." Exiqon will consolidate ongoing development of microRNA (miRNA)-based diagnostic products in its Denmark facilities and seek partners to codevelop and commercialize these products.

News of Exiqon's CLIA lab divestment follows that of Affymetrix (Santa Clara, Calif.). The microarray maker transferred ownership of its 10,000-square-foot Clinical Services Lab to Navigenics (Foster City, Calif.) in early 2009.

Meanwhile, Asuragen (Austin, Texas) is moving forward with its CLIA lab as a key component of efforts to commercialize its miRNA-based cancer tests and conduct clinical sample testing for clients in the pharmaceutical industry. In December, the molecular diagnostics company received accreditation by the Laboratory Accreditation Program of the College of American Pathologists (CAP).

References

Abbott Laboratories 847-937-6100
Affymetrix 408-731-5000
Applied Genomics 256-533-2949
Asuragen 512-681-5200
Becton Dickinson 650-651-3100
BioTrove 781-721-3600
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