



Gene Expression Test from XDx Now Indicated for Earlier Use and Prediction of Acute Cellular Rejection

XDx also receives reimbursement coverage from California Medicare Contractor, National Heritage Insurance Company

South San Francisco, October 31, 2006 – XDx, a molecular diagnostics company, announced today expanded use and reimbursement for its first commercial offering, the AlloMap™ molecular expression test.

Data from a recent study show that AlloMap testing, a non-invasive method to detect the absence of acute cellular rejection in heart transplant recipients can now be used as early as two months post-transplant to rule out rejection. Additionally, patients who are greater than 2 months but less than 6 months post-transplant who have an AlloMap test score below 20 are predicted by the test to be free from acute cellular rejection for 80 days or approximately 12 weeks. These enhancements to the test's indications can help physicians to individualize or tailor patient care, reduce invasive monitoring (biopsies) and their risk of complications, and thereby, improve patient safety.

The California Medicare contractor, National Heritage Insurance Company (NHIC) has recently made a decision to provide reimbursement coverage for the AlloMap test. This decision is effective for claims submitted on or after January 1, 2006. Medicare bills for AlloMap testing are currently billed through NHIC because the test is conducted by XDx in its South San Francisco, California clinical laboratory.

AlloMap testing was clinically validated as a result of data from the Cardiac Allograft Rejection Observational (CARGO) study. The test has been commercially available since January 2005. Before now, the test was available only for patients 6 months or more post transplant. The expanded indication allows physicians to incorporate this non-invasive monitoring tool into their practice upon stabilization of a patient as early as two months post-transplant.

“This breakthrough will enable physicians to significantly improve the monitoring, management and safety of high-risk patients, without causing undue stress or risks from the complications of biopsy,” said Mandeep Mehra, M.D., chief, Division of Cardiology, Herbert Berger Professor of Medicine, University of Maryland Medical Center. “From my experience, molecular testing enables superior confidence in patient management decision-making, and these new data show AlloMap testing can help earlier in the treatment process.”

Biopsies have been used as the standard for routine monitoring of transplant recipients, and patients often undergo 12-14 biopsies during the first year post-transplant. Biopsy is an invasive, painful and expensive procedure, which can detect organ rejection in patients only after damage to the heart tissue has occurred.

(more)

AlloMap testing is a non-invasive alternative to biopsy that is safe, effective, quantitative, and reproducible with predictive capabilities biopsy does not provide. The test provides physicians with a broader clinical picture, enabling them to identify patients at low risk for current and future rejection.

“We’ve incorporated AlloMap testing into our treatment protocol, and now plan to use it instead of biopsies for longitudinal monitoring,” said Dr. Mehra. “Molecular testing will become common practice for heart transplant centers within the next few years, eliminating most, if not all biopsies and as a result, improve the quality of life for our patients.”

“With clinical data and more than one-and-a-half years of real-world use, we’re seeing increased use of AlloMap testing at the top transplant centers nationwide,” said Pierre Cassigneul, president and chief executive officer of XDx. “With this test, we’re fortunate to offer patients a simple, non-invasive, safe and reliable means to manage their care both short- and long-term.”

About XDx

Founded in 2000, XDx is a molecular diagnostics company based in South San Francisco, Calif. Setting the stage for a new era in personalized medicine, XDx is one of the first companies to develop and commercialize practical applications built on insights from the Human Genome Project. The company has developed a proprietary new method for non-invasively monitoring the immune system by measuring gene expression in a patient’s peripheral blood. The technology offers the potential to decrease healthcare costs and significantly improve the quality of life for patients with a variety of life-threatening or life-altering, immune-mediated diseases. More information can be found at www.xdx.com.

About AlloMap™ Molecular Expression Testing

AlloMap molecular expression testing is a non-invasive method for detecting the absence of rejection in heart transplant recipients. AlloMap testing is available only through the clinical laboratory at XDx in South San Francisco, where it was developed and validated. The test translates the complex signals of the immune system’s multiple genes and pathways, specifically those associated with heart transplant rejection, into an objective, actionable score. AlloMap testing enables clinicians – for the first time – to monitor the immune system early, before tissue damage occurs. The clinical value of AlloMap testing was validated with samples and clinical data from a landmark multi-center, prospective study known as the Cardiac Allograft Rejection Gene Expression Observational (CARGO) study. In addition, clinical trials are currently underway to determine the value of AlloMap testing in lung transplantation. The company also plans to evaluate the utility of this technology in autoimmune conditions such as lupus and Crohn’s disease. More information can be found at www.allomap.com.

#

CONTACT:

Corporate:
Tammy Reilly
XDx
650-624-0120

Media:
Kelly McKenna
MS&L
415-278-3318