



NEWS RELEASE

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XDx's AlloMap® Gene Expression Test Cleared by U.S. Food and Drug Administration (FDA)

- XDx Receives FDA Clearance under New FDA IVDMA Guidelines -

BRISBANE, California, August 27, 2008 – XDx, Inc. has received market clearance from the U.S. Food and Drug Administration (FDA) for AlloMap® Molecular Expression Testing. The AlloMap Test is a noninvasive, multi-gene molecular diagnostics blood test used to aid in the identification of heart transplant recipients with stable allograft function who have a low probability of moderate/severe acute cellular rejection at the time of testing, in conjunction with standard clinical assessment. XDx is the first U.S. molecular diagnostics company to obtain FDA clearance of an In Vitro Diagnostic Multivariate Index Assay (IVDMA) for use in transplant management.

“The FDA clearance further demonstrates the clinical relevance and benefit of AlloMap Testing in assessing the potential risk of rejection in heart transplant patients,” stated Pierre Cassigneul, president and chief executive officer of XDx. “This clearance and the FDA's focus on this field underscore the growing importance of molecular diagnostics in the care of patients.”

“AlloMap is a valuable tool in the management of heart transplant patients,” said Dr. Howard J. Eisen, professor and chief of cardiology at Drexel University College of Medicine in Philadelphia. “As a simple blood test, AlloMap can be used on an ongoing basis to help to determine which heart transplant patients are the least likely to suffer from rejection, which is a key factor in the long-term well being and treatment of these patients.”

AlloMap Testing assays the RNA levels of 11 rejection biomarker genes and nine control genes. AlloMap Testing was clinically validated using data from 9 leading heart transplant centers participating in the Cardiac Allograft Rejection Gene Expression Observational (CARGO) study. AlloMap Test has been available since January 2005 as a Laboratory Developed Test (LDT) performed in the XDx Clinical Laboratory

Improvement Amendments (CLIA) certified Laboratory, and has been ordered at more than 50 U.S. transplant centers. The AlloMap Test may be used for stable patients aged 15 years or older at any time after the second month post-transplant. In order to maintain tight control of the testing processes, AlloMap Test is currently performed only at the XDx Reference Laboratory.

“We have worked diligently with the FDA on our 510(k) application since the Agency announced its plans to regulate this new category of molecular diagnostic tests,” stated Mitch Nelles, vice president of research and development and technical operations at XDx. “FDA clearance of AlloMap Testing is a milestone in the emerging field of molecular diagnostics and an affirmation of the XDx approach to develop and commercialize high-value molecular tests for immune-mediated conditions by integrating genomic technologies, clinical expertise and state-of-the-art informatics.”

About AlloMap®

The AlloMap Test is a noninvasive, quantitative, multigene molecular diagnostic blood test that applies a mathematical algorithm comprised of the expression values, or RNA levels, of 20 genes and yields a single AlloMap Test score. This composite score is an integer ranging from 0 to 40 and discriminates between the absence or presence of moderate-to-severe acute cellular rejection.

About XDx

Based in Brisbane, California, XDx is a molecular diagnostics company focused on the discovery, development and commercialization of noninvasive gene expression-based tests for the monitoring of transplant rejection and autoimmune diseases. The company has developed a proprietary new method for noninvasively monitoring immune system activity by measuring gene expression in a patient’s peripheral blood. This work is the basis for AlloMap Molecular Expression Testing, which provides transplant physicians with a new tool to aid in the identification of the probability of acute cellular rejection for postcardiac transplant patient management.

Some of the AlloMap Molecular Expression Technology developed and implemented by XDx in heart transplant patient management may be applicable to other diseases that involve transplant rejection and the immune system. XDx’s noninvasive 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.

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