



# NEWS RELEASE

## FOR IMMEDIATE RELEASE

**Contact:**

Sheryl Seapy, Pure Communications  
(949) 608-0841

### **California Technology Assessment Forum (CTAF) Unanimously Agrees that XDx's AlloMap® for the Diagnosis of Heart Transplant Rejection Meets All Technology Assessment Criteria**

*Panel determines that AlloMap meets criteria for safety, effectiveness, and improvement in health outcomes*

**BRISBANE, CA, November 8, 2010** – XDx, Inc., a molecular diagnostics company focused on noninvasive gene expression tests for the monitoring of immune-mediated conditions, today announced that the California Technology Assessment Forum (CTAF) unanimously agreed that AlloMap® meets all five Technology Assessment Criteria for safety, effectiveness and improvement in health outcomes when used to manage heart transplant patients at least one year post-transplant.

The non-profit CTAF, a public service forum sponsored by Blue Shield of California Foundation with a mission to assess new and emerging medical technology, consists of a panel of 16 medical experts who adhere to a transparent scientific literature review focused on evidence for the safety, effectiveness and improvement in health outcomes of the technology. CTAF concluded that “Gene expression profiling offers the potential for a noninvasive test that may replace endomyocardial biopsy as the gold standard for transplant rejection in stable patients.”

AlloMap is a patented, gene expression test that uses a simple, noninvasive method of blood sample collection and can be used to reliably indicate the low probability of acute cellular rejection in stable heart transplant recipients. It has been commercially available since 2005 and was cleared by the U.S. Food and Drug Administration in 2008.

“We are very excited that after the comprehensive evaluation of the most current scientific literature, CTAF has determined that the AlloMap test meets their criteria for safety, effectiveness and improvement in health outcomes for the assessment of rejection in heart transplant recipients,” stated Pierre Cassigneul, president and chief executive officer of XDx. “CTAF’s independent and unbiased recommendations are an important decision-making resource for clinicians and patients, and the CTAF recommendation further validates AlloMap as an important alternative to invasive endomyocardial biopsy

in the management of stable heart transplant recipients--one that can have a significant impact on patient quality of life.”

CTAF’s decision was based on an intensive review of the clinical data and specifically on the recent publication of the Invasive Monitoring Attenuation by Gene Expression (IMAGE) study results, published in the *New England Journal of Medicine* (<http://www.nejm.org/doi/full/10.1056/NEJMoa0912965>). The IMAGE study is a landmark study in the field of heart transplantation; it is the only large multicenter, randomized controlled trial to study the comparative effectiveness of the traditional endomyocardial method with a non-invasive alternative method of surveillance of patients for rejection. The CTAF decision follows the recent inclusion of AlloMap in the inaugural clinical guidelines issued by the International Society of Heart and Lung Transplantation (ISHLT), which are intended to set the worldwide standard for the care of heart transplant patients.

#### **About AlloMap® Molecular Expression Technology**

AlloMap Molecular Expression Testing is a noninvasive gene expression 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 a standard clinical assessment. AlloMap testing measures the expression levels of 20 genes from a blood sample. The combined expression of these genes is represented as an AlloMap test score. AlloMap is performed in the X Dx CLIA-certified laboratory and has been commercially available since 2005. AlloMap was cleared by the U.S. Food and Drug Administration in 2008.

#### **About X Dx**

X Dx, based in Brisbane, Calif., 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 AlloMap Molecular Expression Testing, an FDA-cleared test, which provides transplant physicians with a tool to aid in the determination of the probability of acute cellular rejection for post-cardiac transplant patient management. Some of the AlloMap technology developed and implemented by X Dx in heart transplant patient management may be applicable to other conditions that involve transplant rejection and diseases that affect the immune system. X Dx’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. For more information, please visit [www.xdx.com](http://www.xdx.com).

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