



Independent Clinical Data Confirms Accuracy of Gene Expression Test for Heart Transplant Patients

Alternative to Invasive Heart-Muscle Biopsy, Simple Blood Test Predicts Absence of Transplant Rejection

Brisbane, Calif., January 22, 2006 – For many Americans living with a heart transplant, invasive heart-muscle biopsies that check for organ rejection are a fact of life. However, a simple blood test that analyzes a patient’s genes, introduced in 2005, has been evaluated by leading transplant centers, and their experience verified that it can accurately detect the absence of heart transplant rejection, according to data from a consensus team of international heart transplant experts that was published in the December 2006 edition of the *Journal of Heart and Lung Transplantation* (JHLT).

In January 2006, results from the CARGO (Cardiac Allograft Rejection Gene Expression Observational) study were published and reported on the utility of a gene expression profiling (GEP) test, called AlloMap[®] molecular expression testing, which had been commercially available for nearly a year. Developed by XDx, a molecular diagnostics company in Brisbane, Calif., the test is currently offered at 40 transplant centers in the United States.

“AlloMap testing is not only less invasive and less risky than biopsy, it also monitors the absence of organ rejection and raises the suspicion of damage before any damage to the heart happens. Biopsy records damage that has already occurred,” said Dr. Mario Deng, the article’s corresponding author. Dr. Deng is director of cardiac transplantation research and associate professor of clinical medicine at Columbia University College of Physicians and Surgeons, and a practicing cardiologist at New York-Presbyterian/Columbia University Medical Center.

Approximately 30 percent of all heart transplant patients reject their new heart at least once in the first year after transplantation. When testing reveals organ rejection, a patient’s immunosuppressive regimen is adjusted.

“The Cleveland Clinic was the first transplant center in the United States to use the AlloMap test to follow patients after cardiac transplant,” said Dr. Randall C. Starling, the editorial’s first author and vice chairman of cardiovascular medicine and section head of heart failure and cardiac transplant medicine at Cleveland Clinic. “There is clearly a need for new methods to determine the best way to manage heart transplant patients. Gene expression profiling appears to be the future, and holds the potential to improve accuracy of diagnosis, reduce the need for invasive procedures and reduce cost. Additional research is necessary, but we are encouraged that gene expression profiling will improve the care of our patients.”

Based on the new data published as an invited editorial, in more than 99 percent of cases, the AlloMap test successfully predicted the absence of moderate or severe acute cellular organ-transplant rejection. These results confirm the findings of the CARGO study.

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The AlloMap test was developed to rule out rejection, meaning that a low test score very reliably identifies transplant patients who are not rejecting their transplanted heart. The primary advantage of the test is to identify low-risk patients who can be monitored and managed using non-invasive methods and may benefit from being more aggressively weaned off of intensive immunosuppressive regimens that are associated with serious side effects.

“Many of the premier transplant centers in the United States have incorporated AlloMap testing into their treatment protocol, and physicians are relying on the test to accurately manage the care of heart transplant recipients,” said Pierre Cassigneul, president and chief executive officer of XDx. “The invited editorial in JHLT further validates the usefulness and accuracy of AlloMap testing. We are pleased to see continued confirmation of the test’s abilities from real-world use.”

The AlloMap test was developed by XDx in partnership with eight major U.S. research universities and presents current immune activity of the transplanted heart recipient. The test uses real-time polymerase chain reaction (PCR) and an algorithm to analyze the patient’s gene expression. The AlloMap test is currently being developed for use in lung transplantation.

Before the availability of AlloMap testing, heart-muscle biopsy was the only method available for detecting rejection of the transplanted heart. Invasive heart biopsies are performed frequently in the first year post-transplant and periodically thereafter, often for the patient’s lifetime.

Currently, the AlloMap test is available to heart transplant patients, ages 15 and older, two months post-transplantation.

Other contributing authors represent more than 20 major U.S. and international heart transplant centers, including Drs. E. Rene Rodriguez, David O. Taylor and H. Mohamed Yamani (Cleveland Clinic, Ohio); Charles C. Marboe (Columbia University, N.Y.); Hannah Valentine and Michael Pham (Stanford University, Calif.); Howard Eisen (Drexel University, Pa.); Jon Kobashigawa (UCLA, Calif.); Kenneth McCurry (University of Pittsburgh, Pa.); Mandeep Mehra (University of Maryland, Md.); Leslie Miller (Fairview University, Minn.); and Andreas Zuckermann (Medical University of Vienna, Austria).

About XDx

XDx’s mission is to improve patient care by developing molecular diagnostics that translate an individual’s immune status into clinically actionable information.

Founded in 2000, XDx is a molecular diagnostics company that utilizes state-of-the-art gene expression technology and sophisticated bioinformatics analyses to understand and measure the immune processes that underlie specific immune-mediated conditions. Physicians can use this information to optimize patient treatment and minimize the long-term consequences of immunosuppressive therapies.

XDx's science and technology is now being evaluated in patients with other solid organ transplants. Building on the discoveries made during the development of AlloMap testing for heart transplant patients, which included the identification of many genes and pathways involved in tissue rejection, XDx is now developing a product for use by physicians to better manage lung transplant patients.

Beyond the use of AlloMap testing in assessing immune response in solid organ transplantation, XDx scientists are applying similar approaches to create new molecular diagnostic tests for the improved clinical management of immune-mediated inflammatory diseases, such as systemic lupus erythematosus (SLE or lupus,) to diagnose and predict clinical flares common in a variety of these diseases.

In addition to its potential for use by physicians for better patient management, the XDx approach is of interest to pharmaceutical companies looking to use biomarkers predictive of drug efficacy in order to proactively identify patient response and to better target their drug development efforts and clinical trials. More information can be found at www.xdx.com.

About AlloMap® Molecular Expression Testing

The first product using this unique approach is AlloMap® molecular expression testing. This service, offered through the XDx CLIA-certified clinical laboratory since January 2005, is being used by a number of leading cardiac transplant centers in the United States to monitor patients following their heart transplants. The scientific and clinical validation of this technology has been described in a peer-reviewed article published in the *American Journal of Transplantation*. More information can be found at www.allomap.com.

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