

Indications For Use

AlloMap Molecular Expression Testing is an In Vitro Diagnostic Multivariate Index Assay (IVDMIA) test service, performed in a single laboratory, assessing the gene expression profile of RNA isolated from peripheral blood mononuclear cells (PBMC). AlloMap Testing is intended to aid in the identification of heart transplant recipients with stable allograft function who have a low probability of moderate/severe acute cellular rejection (ACR) at the time of testing in conjunction with standard clinical assessment.

Indicated for use in patients:

- 15 years of age or older
- At least 2 months (≥ 55 days) since transplantation

Special Considerations

Effect of corticosteroid dosage

Systemic corticosteroid dosage of >20 mg/day of prednisone or equivalent may artificially decrease the AlloMap score (Starling et al., 2006).

Following rejection therapy

The Cardiac Allograft Rejection Gene Expression Observational Study (CARGO) excluded all samples from patients who had received rejection therapy within the past 21 days. The performance characteristics of AlloMap testing in such samples, therefore, have not been established.

Following transfusion

The CARGO study excluded all samples from patients who had received a transfusion within the past 30 days. The performance characteristics of AlloMap testing in such samples, therefore, have not been established.

Questions?

Please call 1-888-AlloMap (1-888-255-6627)
or visit us at www.allomap.com

Incorporating AlloMap® Testing in the Management of Heart Transplant Patients

AlloMap testing expands the decision environment for managing heart transplant patients by adding unique information regarding gene expression levels associated with heart transplant rejection*.

The AlloMap test is performed using a blood sample obtained by routine phlebotomy. A physician receives AlloMap test results as an AlloMap score (integer from 0-40) which is a measure of the expression levels of 20 genes. Each AlloMap score is associated with a Negative Predictive Value.

High Negative Predictive Value

The utility of the AlloMap test in identifying a low probability of rejection is based on its Negative Predictive Value (NPV). The NPV is the probability, expressed as a percent, that the patient is not experiencing rejection at the time of testing. In general, the lower the score, the lower the probability of rejection at the time the blood was drawn from the patient.

Decision Environment for the Management of Heart Transplant Patients

AlloMap Testing	Echocardiography	Right Heart Catheterization	Endomyocardial biopsy
1. Acute Cellular Rejection (ACR) Analysis Type			
Helps identify patients at low probability of ACR at time of testing	Identifies allograft dysfunction that may be associated with ACR	Identifies allograft dysfunction that may be associated with ACR	Helps identify the presence of ISHLT grade $\geq 3A$ (2R)
2. Mechanism of detection			
Gene expression measurement by qRT-PCR	Ultrasound evaluation of graft function	Measurement of chamber and vascular pressure	Pathology grading of tissue samples
3. Invasiveness of the procedure			
Non-invasive (in vitro diagnostic (IVD) test)	Non-invasive	Moderately invasive	Invasive
4. Duration of the procedure (average)			
Minutes (phlebotomy)	<1 hr	hours	hours
5. Time for Result (average)			
1-2 days	Immediate	Immediate	<24 hours
6. Recovery time (average)			
none	none	hours	hours
7. Potential complications of the procedure			
Minimal (typical for phlebotomy)	none	Bleeding, pneumothorax	Scarring, pneumothorax, ventricular perforation, flail tricuspid leaflets, arrhythmias

*The term "rejection" is used to mean "moderate to severe acute cellular rejection" (ACR) and "ISHLT grade $\geq 3A$ (2R)" in this document.