HeartCare®

New ISHLT Guidelines Support Use of HeartCare Solutions, AlloMap® Heart and AlloSure® Heart, in Routine Monitoring of Heart Transplant Patients


Marilyn W., heart transplant recipient

CareDx is the ONLY provider of Gene Expression Profiling (AlloMap Heart) and Donor-Derived Cell-Free DNA (AlloSure Heart) for heart transplant recipients.

The new ISHLT Guidelines* mention the following:

1 Earlier use of AlloMap Heart starting at two months post-transplant based on strength of clinical studies

Recommendations for the Non-Invasive Monitoring of Acute Heart Transplant Rejection

2010 Guideline Recommendation	2023 Update Guideline Recommendation
Gene Expression Profiling (AlloMap) can be used to rule out the presence of ACR of grade 2R or greater in appropriate low-risk patients, starting at 6 months after HT. *Class IIa, Level of Evidence: B*	Gene Expression Profiling (GEP) (i.e., Allomap) of peripheral blood can be used in low-risk patients starting at 2 months after HT to identify adult recipients who have low risk of current ACR to reduce the frequency of EMB. *Class IIa, Level of Evidence: B*

2 AlloMap gene expression profiling (GEP) and donor-derived cell-free DNA (dd-cfDNA) for routine post-transplant monitoring

Frequency of Routine Tests and Clinic Visits in Heart Transplant Recipients

2010 Guideline Recommendation	2023 Update Guideline Recommendation
No mention of non-invasive monitoring in the follow up visits to monitor rejection	Follow-up visits to monitor for rejection may include non-invasive rejection monitoring - Gene Expression Profiling [AlloMap] and donor-derived cell-free DNA. *Class I, Level of Evidence B.*

3 Remote use of GEP and dd-cfDNA heart transplant surveillance (HeartCare), as evidenced during the COVID pandemic

Emerging Pathogens, Epidemics and Pandemic Considerations for Heart Transplant Recipients

2010 Guideline Recommendation	2023 Update Guideline Recommendation
No recommendation	Patient Management During a Pandemic: Efforts should be made to reduce visits by clinically stable heart transplant patients to medical facilities by shifting blood testing to the patients' homes. Remote drawing of blood samples can include screening tests to determine if patients require endomyocardial biopsies using gene expression profiling and donor derived cell-free DNA assays. *Class I, Level of Evidence C*

References to ISHLT are offered solely to support AlloMap's FDA indications and should not be construed as supporting any other use. AlloMap should be solely used in conjunction with standard clinical assessment.

HeartCare is a **Multi-modality Approach** that Utilizes Two Complementary Technologies

HeartCare®

The first and only multi-modality test to provide a comprehensive view of graft injury and immune quiescence

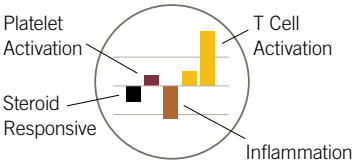
Immune Quiescence	Detection	
	ACR	AMR
+++	+++	+++

AlloMap® HEART + AlloSure® HEART

Gene Expression Profiling

Identify patients with stable allograft function and low probability of cellular rejection

Recipient Immune Activity



Genes in the AlloMap Signature

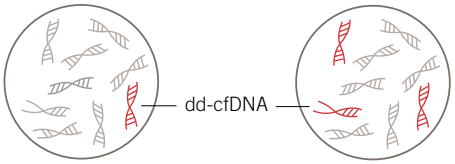
- **Lymphocyte Activation:** SEM7A
- **Cell Migration:** RHOU
- **T Cell Priming:** PDCD1, ITGA4
- **Inflammation (Hematopoietic Proliferation):** MARCH8, WDR40A
- **Steroid Sensitive:** IL1R2, FLT3, ITGAM
- **Platelet Activation:** PF4, C6orf25

Immune Quiescence	Detection
	ACR
+++	++

Donor-Derived Cell-Free DNA

Molecular marker of allograft injury

dd-cfDNA No Graft Injury **dd-cfDNA During Graft Injury**



Detection	
ACR	AMR
++	+++

A History of Leadership and Innovation in Heart Transplantation

90% of Transplant Centers Use AlloMap and 1 in 2 New Heart Transplant Recipients

4500+ Patients Studied Across AlloMap and AlloSure Heart

57+ Journal Publications

FDA AlloMap - FDA 510(k)-cleared to identify recipients at low probability of ACR ≥55 days post-transplant and ≥15 y/o

*Velleca A, Shullo MA, Dhital K, et al. The International Society for Heart and Lung Transplantation (ISHLT) guidelines for the care of heart transplant recipients. *J Heart Lung Transplant.* 2023;42(5):e1-e141. doi:10.1016/j.healun.2022.10.015

Under FDA-cleared labeling, AlloMap is indicated for use in heart transplant patients who are ≥15 years old and ≥55 days post transplant.

The provided information and performance claims may not be consistent with the FDA cleared intended use for AlloMap. Please visit CareDx.com/AlloMap for the FDA cleared intended use for AlloMap

For the latest on HeartCare **visit CareDx.com or email info@CareDx.com**

CareDx® Your Partner in Transplant Care™

LK-10651 Revision 2 Effective 2024-01