

Go Beyond Surveillance Biopsies with HeartCare

The first and only multi-modal test with studies demonstrating a significant reduction in surveillance biopsies and revolutionizing post heart transplant care



Unmet Need

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HeartCare as a Surveillance Tool

Heart Transplant Surveillance is Complex

Risk of long-term complications require a holistic approach

Monitoring Rejection and Beyond with HeartCare

Clinical Studies

Logistics Data

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TOO MUCH IMMUNOSUPPRESSION

Increased risk of:

Infections

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- Kidney injury
- Malignancy
- Post-transplant diabetes

TOO LITTLE IMMUNOSUPPRESSION

Increased risk of:

- Rejection leading to potential failure of the organ
- Cardiac Allograft Vasculopathy (CAV)



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Traditional Tools for Surveillance Monitoring May Not Allow for Early Intervention

This may impact long term outcomes

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Traditional Biopsies Have Significant Limitations for Rejection Surveillance

- Resource intensive
- Risk of exposure to pathogens
- Sampling errors and limitations
- Invasive, painful, and frequent (sometimes >10 Biopsies in the 1st year post-transplant)
- Interobserver variability in interpretation for example:

Almost 40% of rejections called by local pathologists were downgraded when reviewed by a panel of central pathologists

Agreement between local and central pathology for rejection ¹					
	Central Grades				
Local Grades	2R Rejection	< 2R Rejection			
2R Rejection	46/76 (60.5%)	30/76 (39.5%)			
< 2R	63/862 (7.3%)	799/862 (92.7%)			





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HeartCare is a non-invasive leading indicator of graft injury and immune activation/quiescence



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HeartCare Is a Multi-Modality Approach that Utilizes Two Complementary Technologies







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AlloMap Heart is an Established Standard in Heart Transplant

-Allo Map®

90%

Used in 90% of US heart transplant centers and 1 in 2 new patients

📋 ISHLT

Guideline recommended in 2010 and 2023*

NEJM

Extensively validated including publication in NEJM



**When coverage criteria is met



FDA 510(k)-cleared to identify recipients at low probability of ACR \geq 55 days post-transplant and \geq 15 years old

* References to ISHLT are offered solely to support AlloMap's FDA indications and should not be construed as supporting any other use.

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HeartCare Provides Peace-of-Mind During Surveillance



^ Post-transplant Period ≥2-6 months ^^ Post-transplant period ≥6 months * clinical correlation is required

** as defined by their institutional protocol

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The new 2023 ISHLT Guidelines mention the following:

2010 Guideline Recommendation	2023 Update Guideline Recommendation				
Earlier use of AlloMap Heart starting at two months post-transplant based on strength of clinical studies.					
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. <i>Class IIa, Level of Evidence: B</i>	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. <i>Class IIa, Level of</i> <i>Evidence: B</i>				
AlloMap gene expression profiling (GEP) and donor-derived cell-free DNA (dd-cfDNA) for routine post-transplant monitoring.					
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 <i>Class I, Level of Evidence B.</i>				
Remote use of GEP and dd-cfDNA heart transplant surveillance (HeartCare), as evidenced during the COVID pandemic.					
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. <i>Class I, Level of Evidence C</i>				

New ISHLT Guidelines² Support Use of HeartCare

Solutions, AlloMap Heart and AlloSure Heart, in

Routine Monitoring of Heart Transplant Patients

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

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

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HeartCare as a Surveillance Tool

HeartCare Offers a Synergistic Approach to Post-transplant Surveillance



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HeartCare as a Surveillance Tool

High HeartCare Results are Associated with a Higher Chance of ACR

Results from two independent studies^{3,4} demonstrate increased ACR with concordantly elevated HeartCare results



High AlloMap is: \geq 30 for \geq 2-6 months or \geq 34 for \geq 6 months | High AlloSure is \geq 0.2%

Incidence of ACR increases with high HeartCare results

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High HeartCare Results Increased the Odds of ACR by ~14X

Data derived from the combination of two independent single center studies^{3,4}

The chance of a biopsy revealing ACR is greater with a high HeartCare than with either a high AlloMap or a high AlloSure alone



Positive Likelihood Ratio gives the change in the odds of having a diagnosis in patients with a positive test.

A LR+ is mathematically defined as sensitivity / (1-specificity)

High AlloMap is: \geq 30 for \geq 2-6 months or \geq 34 for \geq 6 months | High AlloSure is \geq 0.2%

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ACR Surveillance with HeartCare – Proposed Management^{1,3,4,5}



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HeartCare as a Surveillance Tool

Clinical Interpretation for HeartCare -ACR Surveillance

HeartCare helps clinicians precisely identify patients who are at higher risk of ACR

HIGH ALLOMAP / LOW ALLOSURE	HIGH ALLOMAP / HIGH ALLOSURE		
A biopsy is unlikely to reveal ACR Consider biopsy or repeat HeartCare testing earlier if: • AlloMap elevation is new and AlloSure level has risen or is near threshold Consider other pathological causes of an increased AlloMap:	Relatively high probability that ACR is present Biopsy should be considered 		
Medication adherence review recommended	Medication adherence review recommended		
LOW ALLOMAP / LOW ALLOSURE	LOW ALLOMAP / HIGH ALLOSURE		
Low Likelihood of ACR • A biopsy is unlikely to reveal ACR • Continue protocol immuno-optimization	A biopsy is unlikely to reveal ACR Consider a biopsy or repeat HeartCare testing earlier if: • Recent treatment for rejection (<21 days) or current prednisone >20mg • At risk of Antibody Mediated Rejection / markedly elevated AlloSure level • AlloSure elevation is new and AlloMap level has risen or is near threshold Consider other possible pathological causes of an increased AlloSure: • Cardiac allograft vasculopathy • Severe infection • Antibody Mediated Rejection (AMR) / Donor specific antibodies		
	 Antibody Mediated Rejection (AMR) / Donor specific antibodies Medication adherence review recommende 		

The table is provided for informational purposes only and is not intended as medical advice. A physician's test selection and interpretation, diagnosis, and patient management decisions should be based on his/her education, clinical expertise, current guidelines, and assessment of the patient.

This table is designed for the context of surveillance testing for ACR; For patients that are at risk of AMR or being tested in other clinical context, different guidance may apply. High AlloMap is \geq 30 for \geq 2-6 months or \geq 34 for \geq 6 months | High AlloSure is \geq 0.2%

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When Using HeartCare

Biopsies with HeartCare

Two Independent Studies^{4,6} Demonstrate

Significant Reduction In Surveillance Biopsies



Henricksen et al⁶: 60% Reduction in Biopsies in Year 1 Post-transplant



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HeartCare as a Surveillance Tool

HeartCare Allows for Reduction in Biopsies Without Impacting the Outcomes vs. GEP Alone

This independent study⁶ compares paired use of AlloSure dd-cfDNA and AlloMap GEP testing against GEP testing alone

The results were similar to the post-transplant survival, rejection free survival and graft function at 1 year, while requiring significantly fewer endomyocardial biopsies

Total Biopsies in the First Year Post Transplant



First Year Rejection Free Survival from Acute Cellular Rejection 2R/3R by Protocol



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Clinicians Rely on HeartCare When Making Clinical Decisions

An independent study⁶ shows that clinicians find individual value in AlloMap and AlloSure, and use both tests for patient management

In patients with a High AlloSure and a Low AlloMap, More than 75% of ACR Surveillance biopsies were deferred

Only AlloSure Heart

If 10 Patients had a High AlloSure

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HeartCare Testing

If 10 Patients had a High AlloSure with a Low AlloMap

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Data from Henricksen et al6

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AlloSure Heart Has Been Clinically Validated to Differentiate Rejection vs. No Rejection

AlloSure Heart was clinically validated in the multi-center prospective D-OAR study⁵

Clinical Validation:

- dd-cfDNA levels are over 2X greater in the rejection groups vs. the no rejection group
- No rejection vs. all rejection, p= 0.005



- ACR = Grade 2R and Grade 3R
- Grades OR and 1R are in the No Rejection group
- AMR = pAMR1 and pAMR2

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Monitoring Rejection and Beyond with HeartCare

AlloMap's Surveillance was Compared to Biopsy in the Landmark NEJM Paper⁷

This was followed by the ISHLT-cited elMAGE randomized trial⁸ in which AlloMap was compared to biopsy beginning at 55 days after transplant.



Kaplan-Meier Estimates of the Time to the Composite Primary Outcome (in IMAGE):

This image shows the time to the first occurrence of any of the following primary events: rejection with hemodynamic compromise, graft dysfunction due to other causes, death, or retransplantation. Only the first event that was part of the composite primary outcome was considered.





eIMAGE: Kaplan–Meier curve demonstrating probability of eventfree progression for GEP and EMB groups in the first 18 months post transplant

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AlloSure Heart Can Provide Information on DSA and CAV

REJECTION

Patients with AlloSure Heart levels >0.15% were more likely to develop De Novo DSAs within year 1 post-transplant⁹



Elevated AlloSure Levels are an Independent Predictor for dnDSA (p<0.001)¹⁰



Elevated AlloSure Levels are Associated with Cardiac Allograft Vasculopathy¹¹



Significant CAV was present in 63% of patients with high levels of dd-cfDNA compared to 35% in the low dd-cfDNA group (p=0.047)

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HeartCare Has Been Clinically Validated in Multi-Center Prospective Studies Including >4,500 Patients

2006	Cardiac Allograft Rejection Gene Expression Observation (CARGO) First multicenter validation of GEP test to identify heart txp at low risk mod/severe rejection		N = 222
2010	Invasive Monitoring Attenuation through Gene Expression (IMAGE) Prospective, randomized, controlled, multi-center trial where Surveillance for rejection with AlloMap (gene expression profiling) was compared to routine biopsy (standard of care)	NEJM	N = 602
2015	Early Invasive Monitoring Attenuation through Gene Expression (eIMAGE) Randomized controlled trial comparing GEP to EMB as early as 55 days post transplant	Circ: Heart Fail.	N = 60
2016	CARGO II The CARGO II study validated the CARGO I study findings of GEP score performance in a predominantly European based cohort	Eur Heart J.	N = 472
2019	Outcomes AlloMap [®] Registry (OAR) Registry 5-year follow-up of patients from 2013-2019	JHLT	N = 1,504
2019	Donor-derived cell free DNA Outcomes AlloMap Registry (D-OAR) Subset of patients co-enrolled in OAR Prospective, Multi-center Registry with 26 Centers to determine whether dd-cfDNA level in a HT recipients' blood can differentiate rejection from no rejection	AJT	N = 740
2021	Surveillance HeartCare Outcomes Registry (SHORE) Prospective registry aimed to capture events in patients during their first 5 years post-transplant	In progress	N = 2707

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Invasive Monitoring Attenuation through Gene Expression (IMAGE) was a prospective, randomized, controlled, multi-center trial⁷

Surveillance for rejection with AlloMap® (gene expression profiling) was compared to routine surveillance biopsy (standard of care)





+ AlloSure



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The Evolution of AlloMap \rightarrow AlloSure \rightarrow HeartCare



Early Invasive Monitoring Attenuation through Gene Expression (eIMAGE) was a single center, randomized, parallel 2-arm study beginning at 55 days post heart transplant.⁸

- The primary endpoints between GEP and EMB groups were compared (p= .45)
- Components of the composite primary endpoints were: first year IVUS results and 1 year echo LV ejection fraction
- Patient satisfaction score for method of surveillance at 1-year was higher in the GEP vs. EMB group (p = .003)



AlloSure

Kaplan–Meier curve demonstrating probability of eventfree progression for GEP and EMB groups in the first 18 months post transplant

Primary endpoint (composite): death or re-transplantation, hemodynamic compromise with rejection, graft dysfunction (hemodynamic compromise without rejection) **Co-primary endpoint:** first-year IVUS changes post-transplant SKIP TO Section:

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Donor-Derived Cell-Free DNA-**O**utcomes **A**lloMap **R**egistry (**D**-**O**AR) was a prospective, multi-center registry with 26 centers to determine whether dd-cfDNA level in a HT recipients' blood can differentiate rejection from no rejection.⁵

AlloSure levels were over 2x greater in the rejection groups vs. the no rejection group



ACR = 2R and 3R; AMR = pAMR1 and pAMR2

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HeartCare - Summary

Proven multi-modality surveillance for heart transplant recipients.

HeartCare can be used to provide a comprehensive overview of graft injury and immune quiescence.



HeartCare can be used for post-transplant surveillance to identify stable patients who are at a higher than anticipated risk of current rejection



HeartCare can also better distinguish between the subset of the population with a higher probability of rejection than either AlloMap or AlloSure Heart alone



Two independent publications have demonstrated that with HeartCare, the avoidance of biopsies is superior to either AlloMap or AlloSure Heart alone

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HeartCare Can Be Used For Longitudinal Surveillance

The Heart Allograft Routine Testing Schedule (HARTS)

The Heart Allograft Routine Schedule is recommended based upon the use of AlloMap in the IMAGE and elMAGE trials and use in clinical practice. All testing should be performed when medically necessary, in accordance with a physician's guidance. The SHORE registry study is assessing the clinical utility of this testing interval.

HARTS Timeline



*Under FDA-cleared labeling, AlloMap is indicated for use in heart transplant patients who are ≥15 years old and ≥55 days post transplant. All specimens submitted for testing and billed to third party payers must support the medical necessity of testing when a test is ordered consistent with clinical judgment and applicable payer policies https://clinicaltrials.gov/ct2/show/NCT03695601

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AlloMap



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Real-World HeartCare Surveillance*

The Stanford University heart transplant protocol for rejection surveillance

Time	Surveillance	Donor Specific Antibody	Echocardiogram	Right Heart Catheterization
Week 2	Biopsy	If antibody crossed	—	Yes
Week 3	Biopsy	If antibody crossed	_	Yes
1 month	AlloSure/Biopsy	Yes	Limited	Yes
Week 6	AlloSure/Biopsy		_	Yes
2 months	HeartCare or Biopsy		Limited	Yes
3 months	HeartCare or Biopsy	Yes	_	Yes
4 months	HeartCare or Biopsy		Limited	
5 months	HeartCare or Biopsy		_	
6 months	HeartCare or Biopsy	Yes	Limited	_
8 months	HeartCare or Biopsy		_	
10 months	HeartCare or Biopsy	Yes	_	_
12 months	HeartCare or Biopsy	Yes	Full or DSE if no angiogram	Yes
15 months	HeartCare or Biopsy		_	_
18 months	HeartCare or Biopsy		Limited	
21 months	HeartCare or Biopsy		_	_
24 months	HeartCare or Biopsy	Yes	Full or DSE if no angiogram	Yes (if angiogram)

*This protocol is provided as an example only. All clinical decisions should be made directly by the referring provider. DSE: Dobutamine Stress Echocardiogram

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Sample Report - HeartCare

 Individual test results (AlloMap or AlloSure Heart) are released when available on individual reports

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 Combined HeartCare results are provided on an integrated report that includes both AlloMap and AlloSure Heart when both test results are available



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Ordering HeartCare

HeartCare may be ordered in several ways:

CarePortal

HeartCare may be ordered electronically, via the CarePortal. One-time tests or custom orders are available through the portal.



HeartCare Test Requisition Form (TRF)

A paper test requisition form is available for ordering HeartCare. Please contact Customer Care for delivery of the hardcopy HeartCare TRFs



Direct EMR Integration

HeartCare may be ordered directly from a hospital EMR by integrating with CareDx's lab software



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Solutions Throughout the Transplant Journey



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CareDx is Your Dedicated Partner in Transplant Care

CareDx supports our providers and patients by providing dedicated Patient Care Managers to facilitate appointment scheduling and blood draw logistics at no additional cost.*

Services

Patient Care Managers

Our Patient Care Managers include nurses and former transplant coordinators who understand the complexity in managing heart transplant patients.

RemoTraC[®]

CareDx provides mobile phlebotomy services for patient tests. There are no additional out of pocket costs beyond any coinsurance or deductible required by the patient's health plan.

MedActionPlan

CareDx offers a robust medication adherence platform to support transplant patients with better medication adherence to optimize their transplant outcomes



^{*}CareDx provides specimen collection through mobile phlebotomists as part of its laboratory service so patients should not have additional out of pocket expenses beyond any coinsurance/deductibles required by their health plans for the test



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