TAI DIAGNOSTICS

Monitoring the Health of Transplanted Organs

PRODUCT OVERVIEW

myTAI HEART

Test Description

The myTAI$_{HEART}$ test uses a panel of single nucleotide polymorphisms to quantitatively genotype cell-free DNA (cfDNA) in the patient's plasma. This measurement accurately distinguishes "donor specific" cfDNA originating in the engrafted heart from "self-specific" cfDNA originating in the recipient's native cells. The myTAI$_{HEART}$ test reports the ratio of donor specific cfDNA to total cfDNA as the donor fraction (%) and categorizes the patient as at low or increased probability of moderate (grade 2R) to severe (grade 3R) acute cellular rejection. The patient's total cfDNA concentration is also reported, along with historical patient results and individualized comments from TAI Diagnostics' Medical Director.

Intended Use

The myTAI$_{HEART}$ test is a laboratory developed test (LDT) performed in a single CAP and CLIA-accredited laboratory which measures the donor fraction of cfDNA in plasma separated from a whole blood sample as a marker for transplanted organ injury. This test is intended to aid in the identification of heart transplant recipients who have a low probability of moderate/severe acute cellular rejection (grade 2R or higher) at the time of testing in conjunction with standard clinical assessment. This test is indicated for use in heart transplant recipients who are 2 months of age or older and ≥ 8 days post-transplant.

EARLY POST-TRANSPLANT SURVEILLANCE

The myTAI$_{HEART}$ test is indicated for use as early as 8 days post-transplant.

PEDIATRIC + ADULT

The first non-invasive transplant rejection monitoring test that can be used in infants and children as well as adults.

SAMPLE INTEGRITY ASSURANCE

Rapid specimen processing methodology with clinically validated myTAI DNA Fragmentation Analysis as an additional quality control measurement.

WIDENED APPLICABLITY

The myTAI$_{HEART}$ test is ideal for monitoring patients when limited vascular access or other clinical limitations preclude biopsy.

RAPID RESULTS

Actionable results are reported to the ordering physician the next business day after receipt at TAI Diagnostics.

CELL-FREE DNA

Quantifies the cfDNA donor fraction (DF), a direct indicator of selective injury to the donor organ. Both the DF and total cfDNA values are reported.

SENSITIVE DETECTION

Increased ability to detect evolving rejection before clinical symptoms develop.

NON-INVASIVE

Safe and cost effective with minimal patient discomfort. Requires only a small blood sample for processing.

CAP ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS

This test was developed and its performance characteristics determined by TAI Diagnostics. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes and should not be regarded as investigational or for research. TAI Diagnostics is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical laboratory testing.

myTAI$_{HEART}$ ® Peer-Reviewed Publications

1. Cell-Free DNA Donor Fraction Analysis in Pediatric and Adult Heart Transplant Patients by Multiplexed Allele-Specific Quantitative PCR: Validation of a Rapid and Highly Sensitive Clinical Test for Stratification of Rejection Probability. North PE, Ziegler E, Mahnke DK, Stamm KD, Thomm A, Daft P, Goetsch M, Liang HL, Baker MA, Vepraskas A, Rosenau C, Dasgupta M, Simpson P, Mitchell ME, Tomita-Mitchell A. PLOS ONE. 2020 January 13; 15(1): e0227385. https://doi.org/10.1371/journal.pone.0227385 PMID: 31929557

2. Donor Fraction Cell-Free DNA and Rejection in Adult and Pediatric Heart Transplantation. Richmond ME, Zangwill SD, Kindel SJ, Deshpande SR, Schroder JN, Bichell DP, Knecht, Mahle WT, Wigger MA, Gaglianello NA, Pahl E, Simpson PM, Dasgupta M, North PE, Hidestrand M, Tomita-Mitchell A, Mitchell ME. J Heart Lung Transplant. 2019 November 29; pii:S1053-2498(19)31767-x. https://doi.org/10.1016/j.healun.2019.11.015. (Epub ahead of print) PMID:31983667

3. Early Changes in Cell-free DNA Levels in Newly Transplanted Heart Transplant Patients. Zangwill SD, Kindel SJ, Ragalie WS, North PE, Pollow A, Hidestrand M, Tomita-Mitchell A, Stamm KD, Mitchell ME. Pediatric Transplantation. 2019 December 11; e13622. https://doi.org/10.1111/petr.13622. PMID: 31825144

4. Effect of Endomyocardial Biopsy on Levels of Donor-Specific Cell-Free DNA. Zangwill SD, Stamm KD, Hidestrand M, Tomita-Mitchell A, Mitchell ME. J Heart Lung Transplant. 2019 October; 38(10):1118-1120. https://doi.org10.1016/j.healun.2019.06.005. Epub 2019 June 28. PMID: 31324442

5. Noninvasive Assay for Donor Fraction of Cell-Free DNA in Pediatric Heart Transplant Recipients. Ragalie WS, Stamm KD, Mahnke D, Liang HL, Simpson P, Katz R, Tomita-Mitchell A, Kindel SJ, Zangwill S, Mitchell ME. J Am Coll Cardiol. 2018 June 26; 71(25):2982-2983. https://doi.org/10.1016/j.jacc.2018.04.026. PMID: 29929623

6. Highly Sensitive Non-invasive Cardiac Transplant Rejection Monitoring Using Targeted Quantification of Donor-Specific Cell-Free Deoxyribonucleic Acid. Hidestrand M, Tomita-Mitchell A, Hidestrand PM, Oliphant A, Goetsch M, Stamm KD, Liang HL, Castleberry C, Benson DW, Stendahl G, Simpson M. Berger S. Tweddell JS, Zangwill S, Mitchell ME. J Am Coll Cardiol. 2014 April 1; 63(12):1224-1226. https://doi.org10.1016/j.jacc.2013.09.029. Epub 2013 October 16. PMID: 24140666

Published Abstracts are also available at: www.taidiagnostics.com