

PRODUCT OVERVIEW

Test Description

The myTAI_{HEART} test is designed to categorize heart transplant patients as at low versus increased risk of acute cellular rejection (ISHLT Grade 2R or higher) when used in conjunction with standard clinical assessment. myTAI_{HEART} quantifies circulating cell-free DNA (cfDNA) in a blood sample and measures its donor fraction (DF), defined as the ratio of donor specific cfDNA to total cfDNA. The patient's donor fraction (%) and total cfDNA concentration are reported, along with historical patient results and individualized comments from TAI's Medical Director.

Intended Use

myTAI_{HEART} is a laboratory developed test (LDT) developed and performed in a single CAP and CLIA-accredited laboratory which measures the donor fraction and total concentration of cfDNA in plasma separated from a whole blood sample. myTAI_{HEART} is indicated for use in heart transplant recipients who are 2 months of age or older and at least 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 APPLICABILITY

myTAI_{HEART} 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.