TAI DIAGNOSTICS *Monitoring the Health of Transplanted Organs*

PRODUCT OVERVIEW

myTAI HEART

Test Description

The myTAI$_{HEART}$ test uses a panel of highly informative 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 versus increased risk of acute cellular rejection (Grade 2R or higher). Results and additional data are provided to the ordering clinician on the TAI Diagnostics - myTAI$_{HEART}$ Results Report.

Intended Use

myTAI$_{HEART}$ is a laboratory developed test (LDT) performed in a single 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 at least 8 days post-transplant.

CELL-FREE DNA

TAI Diagnostics' technology precisely quantitates DNA released by injured heart cells into the bloodstream as a direct measurement of transplant injury.

EARLY SURVEILLANCE

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

PEDIATRIC / ADULT

myTAI$_{HEART}$ is the first non-invasive organ specific rejection monitoring test that can be used in infants and children (as young as 2 months of age).

NON-INVASIVE

myTAI$_{HEART}$ is a non-invasive test that requires a small volume of blood for processing in TAI Diagnostics' accredited clinical reference laboratory.

LIMITED VASCULAR ACCESS

myTAI$_{HEART}$ also addresses the need for monitoring patients with limited vascular access prohibiting biopsy.

RAPID RESULTS

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

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About TAI Diagnostics, Inc.

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. It should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical laboratory testing.

10101 Innovation Drive. STE 600. Wauwatosa, WI 53226 • P: 888-214-3151 • F:888-300-9674 • Email: customersupport@taidiagnostics.com
www.taidiagnostics.com