

MMDx Heart

A New Era of Precision Medicine

The Molecular Microscope® Diagnostic System for Heart (MMDx® Heart) combines the technology of molecular phenotyping with the power of big data to deliver objective and reproducible transplant biopsy assessments.

Based on over a decade of research, MMDx Heart uses artificial intelligence to compare the molecular features of a new biopsy to a reference set, which consists of over 880 heart samples.

The reference set incorporates data from early post-transplant to more than 30 years post-transplant for a more comprehensive understanding of disease states in the transplanted organ.

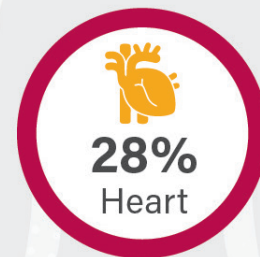
Concordance to Histological Biopsy Diagnosis

Histopathology scores are the primary tool for diagnosing injury or rejection, but studies show frequent disagreement in histological TCMR diagnosis. Additionally, the quality of the biopsy samples can sometimes impact histology results, rendering the samples unreadable.

MMDx Heart is not intended to replace histology. Rather, it **can be used in addition to a histopathologist's assessment**, especially for the objective assessment of challenging cases.

Variability in TCMR Diagnosis with Histopathology

When assessing the same heart biopsy sample, research shows that only **28%** of pathologists will agree on a TCMR diagnosis¹.



A Comprehensive Biopsy Assessment for All Heart Transplant Patients

MMDx Heart **can be used immediately in post-transplant care** for all donor types. By profiling the gene expression in the donor DNA, the test can assess whether the graft is demonstrating signs of an immune response and can in fact characterize the nature of the disease state. The test can be applied to a small sample of the existing biopsy for confirmatory results or for a clearer diagnosis in challenging cases.

Advantages of MMDx Heart

As the latest advancement for the assessment of graft biopsies, MMDx is a convenient and more accurate method for developing the best treatment plan for transplant patients.

- **Actionable data:** Provides objective, quantitative, probabilistic risk assessment
- **Fast turnaround:** Results available within 48 hours after receipt of sample
- **Easily incorporated:** Sample is taken from the existing biopsy and requires sample of only 1-2 bites
- **Efficient process:** Simply put biopsied tissue into the provided tube (containing RNeasy[®]) and ship at room temperature

New Studies on Molecular Assessment for Graft Function

MMDx Heart has demonstrated an improved sensitivity for the detection of subclinical graft injury in heart patients² and for the detection of antibody-mediated rejection (ABMR)³. Molecular assessment may also provide greater clarity for biopsies with high probability of molecular injury but no molecular rejection, a state that can often be misdiagnosed as rejection by histology⁴.

References

¹ Crespo-Leiro MG, et al. Transplant 2012.

² AP Nikolova, JA Kobashigawa. Donor-specific antibodies in heart transplantation: can we afford the price or is it too steep to pay? Curr Opin Organ Transplant. 2020 Dec;25(6):555-562. doi: 10.1097/MOT.0000000000000818. PMID: 33044348.

³ VP Nguyen, JA Kobashigawa. Antibody-mediated rejection after heart transplantation: diagnosis and clinical implications. Curr Opin Organ Transplant. 2020 Jun;25(3):248-254. doi: 10.1097/MOT.0000000000000754. PMID: 32304428.

⁴ PF Halloran et al. Exploring the cardiac response to injury in heart transplant biopsies. JCI Insight. 2018 Oct 18;3(20):e123674. doi:10.1172/jci.insight.123674. PMID:30333303; PMCID: PMC6237487.

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