



MMDx Heart

A New Era of Precision Medicine

The Molecular Microscope Diagnostic System for Heart (MMDx® Heart) combines the technology of high throughput gene expression profiling with the power of big data to deliver reproducible transplant biopsy assessments.

Based on over a decade of research, MMDx Heart uses machine learning algorithm to compare the molecular signatures of a new biopsy to a fixed reference set of heart biopsy samples.

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

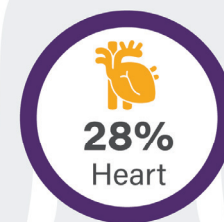
Concordance to Histological Biopsy Diagnosis

Histopathology scores are the primary tool for diagnosing injury or rejection, but studies show frequent disagreement in histological TCMR diagnosis¹. Additionally, biopsy sample quality can impact histology results, sometimes rendering 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 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 requires only two tissue bites for robust and reproducible results. Through gene expression profiling, this test assesses the likelihood of an allograft demonstrating rejection and/or injury, providing probability scores for T-cell mediated rejection (TCMR), antibody mediated rejection (ABMR), recent injury, and late injury (atrophy fibrosis).

Advantages of MMDx Heart

The MMDx platform provides reproducible results and offers the possibility for increased confidence and accuracy in evaluating transplant recipients.

- **Actionable data:** Provides probabilistic risk assessment.
- **Fast turnaround:** Results available within 48-72 hours after receipt of sample.
- **Easily incorporated:** Requires only 2 of the total tissue bites obtained.
- **Efficient process:** Simply put biopsied tissue into the provided tube (containing RNAlater™) 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

⁵ Halloran, P. F., & Madill-Thomsen, K. S. (2023). The molecular microscope diagnostic system: Assessment of rejection and injury in heart transplant biopsies. Transplantation, 107(1), 27–44. <https://doi.org/10.1097/tp.0000000000004323>

⁶ Halloran, P. F., et al. (2024). Redefining the molecular rejection states in 3230 heart transplant biopsies: Relationships to parenchymal injury and graft survival. American Journal of Transplantation, 24(8), 1414–1426. <https://doi.org/10.1016/j.ajt.2024.03.031>

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