MMDx Lung

A New Era of Precision Medicine

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

Based on over a decade of research, MMDx Lung uses artificial intelligence to compare the molecular signatures of a new biopsy to a fixed reference set of transbronchial biopsy samples.

The reference set includes biopsies with a median time of biopsy post-transplant of 329 days, ranging from 4 to 7261 days post-transplant, and age at time of transplant ranging from 10 to 78 years old, allowing for a relatively comprehensive evaluation of allograft disease states[2].

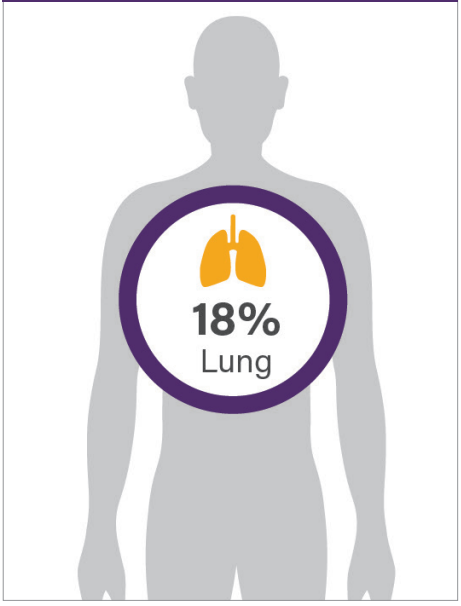
Concordance to Histological Biopsy Diagnosis

Histopathology scores are the primary tool for diagnosing injury or rejection, but studies show frequent disagreement in histological TCMR diagnosis[1]. Additionally, biopsy sample quality can impact histology results, sometimes rendering samples unreadable.

MMDx Lung 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 lung biopsy sample, research shows that only **18%** of pathologists will agree on a TCMR diagnosis[1].



A Comprehensive Biopsy Assessment for All Lung Transplant Patients

Through allograft gene expression profiling, this test assesses the probability of a biopsy specimen demonstrating rejection, while also identifying chronic lung allograft dysfunction (CLAD) related molecular changes. As opposed to the 5 or more transbronchial biopsy bites recommended for histopathology evaluation, MMDx Lung requires two or more of the total biopsy bites obtained for robust and reproducible results.

Advantages of MMDx Lung

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

- **Actionable data:** Provides probabilistic risk assessment
- **Fast turnaround:** Results available within 72 hours after receipt of sample
- **Easily incorporated:** Requires only 2 of the transbronchial 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

The mechanisms involved in pulmonary allograft injury and rejection are poorly understood, and histological assessment of transbronchial biopsies (TBB) offer limited reproducibility and present considerable risk[2]. MMDx Lung offers new insights into these disease states and generates assessment in every TBB with only two tissue bites, quantifying the probability of rejection as well as identifying the molecular features associated with chronic lung allograft dysfunction (CLAD)[2].

References

[1]Arcasoy, S.M. et al. (2011). Pathologic interpretation of transbronchial biopsy for acute rejection of lung allograft is highly variable. American Journal of Transplantation 11, 320-328. doi: 10.1111/j.1600-6143.2010.03382.x

[2]Gauthier, P. T., et al. (2023). Defining a natural killer cell-enriched molecular rejection-like state in lung transplant transbronchial biopsies. American Journal of Transplantation, 23(12), 1922–1938. https://doi.org/10.1016/j.ajt.2023.06.003

[3]Gauthier, P.T., et al. (2025). Assessing molecular rejection with cell type deconvolution in lung allograft transbronchial biopsies. The Journal of Heart and Lung Transplantation 44, S160.

[4]Parkes, M.D., et al. (2021). Transcripts associated with chronic lung allograft dysfunction in transbronchial biopsies of lung transplants. American Journal of Transplantation, 22(4), 1054–1072. https://doi.org/10.1111/ajt.16895

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