MMDx Kidney

A New Era of Precision Medicine

The Molecular Microscope Diagnostic System for Kidney (MMDx® Kidney) 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 Kidney uses machine learning algorithm to compare the molecular features of a new biopsy to a reference set.

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

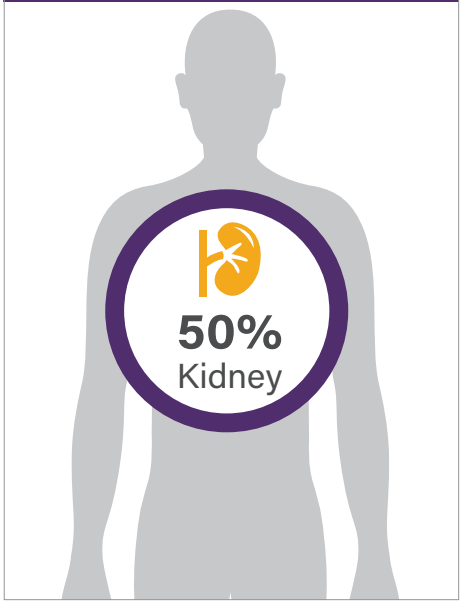
Concordance to Histological Biopsy Diagnosis

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

MMDx Kidney 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 Diagnosis with Histopathology

When assessing the same kidney biopsy sample, research shows that only 50% of pathologists will agree on a TCMR diagnosis[2].



A Comprehensive Biopsy Assessment for All Kidney Transplant Patients

The assessment can be applied to a small sample of the existing biopsy. While cortical samples are preferred, the test can read samples containing both medulla and cortex, which may reduce the risk of an "inadequate" biopsy sample and, as a result, the need for a second biopsy.

Advantages of MMDx Kidney

MMDx Kidney may be included in a comprehensive post-transplant assessment plan as it offers reproducible data.

- **Fast turnaround:** Results available in 24-48 hours after receipt of sample.
- **Easily incorporated:** Sample is taken from an existing biopsy core; only 3-5 mm of tissue is needed.
- **Actionable data:** Simplified reports provide straightforward interpretation of results.

New Studies on Molecular Assessment for Graft Function

In kidney patients with chronic active antibody-mediated rejection (caABMR) and a high degree of chronicity, molecular evidence of rejection has been used to track responses to immunosuppressive therapies and identify response to treatment, as evidenced by improved inflammation[3].

Inflammation in areas of atrophy-fibrosis (i-IFTA) has shown to be associated with increased risk of failure in kidney biopsies. A recent study has concluded that i-IFTA in indication biopsies reflect current or ongoing parenchymal injury, either with TCMR or (more commonly) with concomitant ABMR[4].

MMDx Kidney has demonstrated accuracy and reproducibility in kidney biopsy assessment with minimal inter-observer disagreement in reporting. As a result, MMDx may be particularly valuable in cases when pathology results are borderline or suspicious[5].

References

[1] Callemeyn J, Ameye H, Lerut E, Senev A, Coemans M, Van Loon E, Sprangers B, Van Sandt V, Rabeyrin M, Dubois V, Thaunat O, Kuypers D, Emonds MP, Naesens M. Revisiting the changes in the Banff Classification for antibody-mediated rejection after kidney transplantation. Am J Transplant. 2020 Dec 31. doi: 10.1111/ajt.16474. Epub ahead of print. PMID: 33382185.

[2] Reeve J, et al. Am J Transplant 2013.

[3] D Kumar et al. Impact of Belatacept Conversion on Renal Function, Histology, and Gene Expression in Kidney Transplant Patients With Chronic Active Antibody-mediated Rejection. Transplantation. 2021 Mar 1;105(3):660-667. doi: 10.1097/TP.0000000000003278. PMID: 32510913.

[4] Halloran PF et al. Molecular phenotype of kidney transplant indication biopsies with inflammation in scarred areas. Am J Transplant. 2019 May;19(5):1356-1370. doi: 10.1111/ajt.15178. Epub 2018 Dec 13. PMID: 30417539.

[5] Madill-Thomsen K et al; MMDx-Kidney Study Group. Discrepancy analysis comparing molecular and histology diagnoses in kidney transplant biopsies. Am J Transplant. 2020 May;20(5):1341-1350. doi: 10.1111/ajt.15752. Epub 2020 Jan 23. PMID: 31846554.

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