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MMDx Kidney

A New Era of Precision Medicine

The Molecular Microscope® Diagnostic System for Kidney (MMDx® Kidney) 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 Kidney uses artificial intelligence to compare the molecular features of a new biopsy to a reference set, which consists of over 1,200 kidney samples.

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 ABMR1 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 objective 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

MMDx **can be used immediately in post-transplant care** for all donor types. 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

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 3-5 mm
- **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

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

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[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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