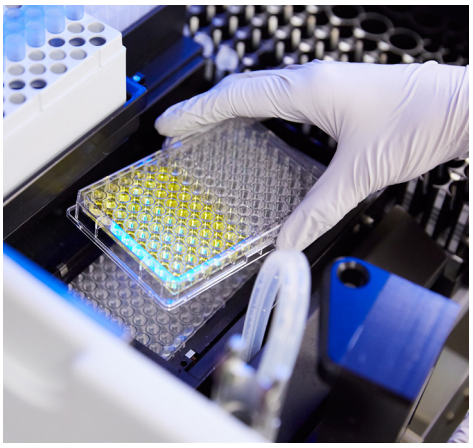
Cincinnati Children's
changing the outcome together

Advancing Precision in IgA Nephropathy

Gd-IgA1 Biomarker Screening Now Available



Clinical Utility

This serum-based assay provides a robust platform for:

- Early detection of IgAN in at-risk populations
- Phenotyping patients for clinical trials and longitudinal studies
- Monitoring therapeutic response to immunomodulatory agents
- Differentiating IgAN from other glomerulopathies with overlapping clinical features

Clinical & Research Applications

This test is intended for:

- Patients with hematuria or proteinuria of unknown origin
- Individuals with a family history of IgAN
- Those under evaluation for chronic kidney disease (CKD)
- Transplant teams assessing risk of recurrent IgAN
- Researchers and sponsors designing biomarker-driven or precision IgAN studies

Clinical Performance

A clinically validated reference range and cutoff have been established using samples from patients with IgAN and healthy controls.

- Diagnostic cutoff: 83.2 µg/mL
- AUC: 0.950
- Sensitivity: 82.9%
- Specificity: 91.6%
- Diagnostic efficiency: 89.8%

Methodology

Assay Type: High-sensitivity ELISA

Detection: Combines IgA-capture reagent with a lectin-based detection of galactose-deficient O-glycans of IgA1

Sample Type: Serum

Turnaround Time: 24–48 hours

Validation: CAP, CLIA, GCLP

To establish institutional access or order testing:

Visit www.cincinnatichildrens.org and search *"Nephrology Diagnostic Lab"*, or call 513-636-4530.

About the Test

The Nephrology Clinical Laboratory at Cincinnati Children's is now offering a clinical assay for Galactose-deficient IgA1 (Gd-IgA1)—a validated biomarker implicated in the pathogenesis of IgA Nephropathy (IgAN).

Gd-IgA1 plays a central role in the multi-hit hypothesis for the basis of IgAN, serving as the autoantigen that forms pathogenic immune complexes. Elevated serum levels are strongly associated with disease onset, progression, and post-transplant recurrence.

TMP1572257 0725