

A novel automated immunoassay for anti-nephrin autoantibodies using a mutant nephrin antigen

Methods

Nephrin Antigen Design:



Free-cysteine

Mutants: all free-cysteines \Rightarrow serine/alanine/valine

Automated Assay System:

HISCL-5000*

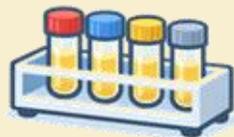


*Automated Immunoassay System HISCL-5000, Pre-market Notification Number: 28B1X10014000011, Marketing Authorization Holder: Sysmex Corporation

Pediatric Clinical Samples:

Nephrotic syndrome cases, n=32

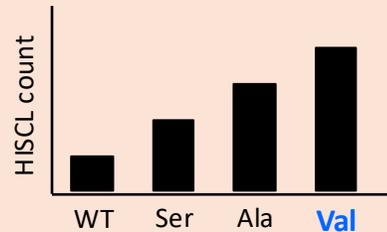
Disease controls, n=30



Results

1. Reactivity of antigens

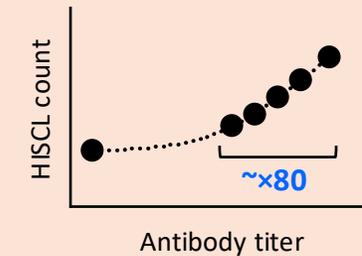
All mutants > Wild-type antigen



2. Analytical Performance Evaluation

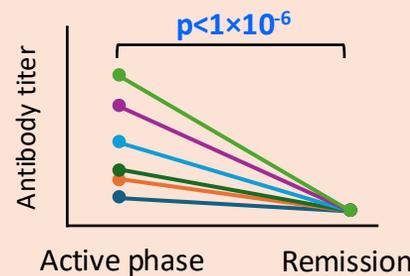
A wide quantitative range

High reproducibility
(intra-, inter-assay CV < 6%)

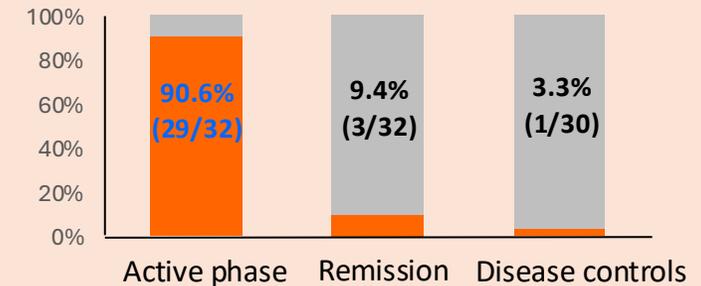


3. Clinical Performance Evaluation

Antibody levels



Antibody positivity rates



Data on file, Sysmex Corporation.

Conclusion: This novel automated immunoassay using a mutant nephrin antigen showed high sensitivity, strong reproducibility, and clear discrimination between active and remission phases of nephrotic syndrome, supporting its potential as a reliable clinical biomarker.

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