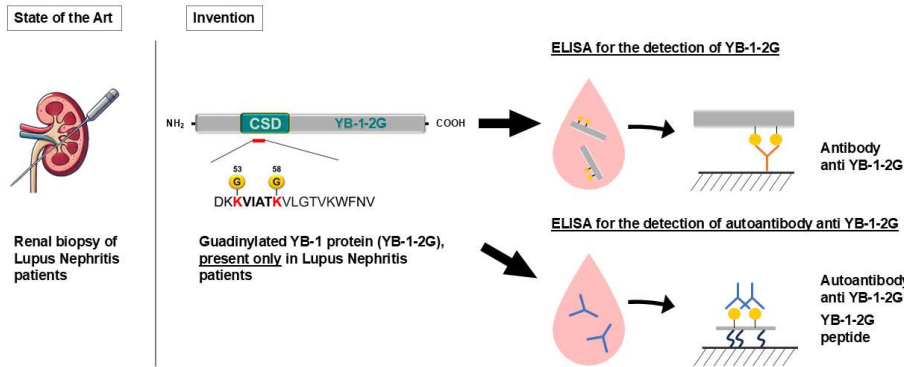


Innovative ELISA Assays for Non-Invasive Lupus Nephritis Diagnosis

Novel YB-1-2G and Anti YB-1-2G Detection Methods for Improved Patient Care

Invention



Subject matter of the invention is a guanidylated YB-1 protein detected by ELISA (antibody against YB-1-2G or anti-YB-1-2G autoantibodies).

Systemic lupus erythematosus (SLE) is a chronic autoimmune disease with a prevalence of 20-50 per 100,000 individuals in European cohorts. Up to half of patients develop Lupus Nephritis (LN), and 10-20% of those progress to end-stage renal failure requiring dialysis. Although anti-dsDNA antibodies are well-established for diagnosing and monitoring SLE, the current reliance on kidney biopsies to confirm LN highlights an urgent need for a reliable, non-invasive diagnostic method.

Existing approaches do not offer a validated biomarker to detect kidney involvement in SLE. To address this limitation, recent analyses of an SLE cohort identified a specifically guanidylated form of the protein YB-1 (YB-1-2G), detectable in serum at particularly high levels in patients with active SLE and LN. Corresponding autoantibodies (Anti YB-1-2G) were also detected. Based on these results, two Enzyme-Linked Immunosorbent Assay (ELISA)-based approaches are currently in development:

1. An ELISA for detecting YB-1-2G in serum, initially using a polyclonal antibody with plans to transition to a monoclonal antibody for greater specificity.
2. A second ELISA to identify circulating autoantibodies against YB-1-2G.

These innovations are designed to significantly improve patient care by providing a non-invasive diagnosis of LN.

Commercial Opportunities

On behalf of the Rheinisch-Westfälische Technische Hochschule (RWTH) Aachen, PROvendis offers an access to rights for ELISA development and commercial use.

Current Status

An ELISA with a polyclonal antibody is currently being developed, but the switch to a monoclonal antibody would have to be made with a company. A multicentre study with patients is planned.

Relevant Publications

We can provide patent status information on request.
Breitkopf DM, Jankowski V, Ohl K, Hermann J, Hermert D, Tenbrock K, Liu X, Martin IV, Wang J, Groll F, Gröne E, Floege J, Ostendorf T, Rauen T, Raffetseder U. The YB-1:Notch-3 axis modulates immune cell responses and organ damage in systemic lupus erythematosus. *Kidney Int.* 2020 Feb;97(2):289-303. doi: 10.1016/j.kint.2019.09.031. Epub 2019 Oct 30. PMID: 31882173.

An invention from the Rheinisch-Westfälische Technische Hochschule (RWTH) Aachen.

Advantages

- Non-Invasive detection
- Diagnosis via established method possible
- Lifesaving diagnosis: Earlier detection of Lupus Nephritis

Technology Readiness Level

1 2 3 4 5 6 7 8 9
Experimental proof of concept

Sector(s)

- Diagnostic

Ref.-No.

5758



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