AI-LFA GBM

Rapid assay for the qualitative determination of anti-glomerular basement membrane (GBM) IgG autoantibodies in human serum or plasma

Anti-Glomerular basement membrane (GBM) autoantibodies, also referred to as Goodpasture antibodies, are highly specific for anti-GBM-Nephritis. In about 75% of all cases, these autoantibodies are associated with the Goodpasture syndrome, characterized by glomerulonephritis and lung hemorrhage. The structure targeted by the immune system is the C-terminal globular domain (NC1) of the α3-chain of collagen IV. This collagen subunit is predominantly located in the basal membranes of kidney and lung. The Goodpasture syndrome is a medical emergency with a case fatality rate of 75 to 90 % due to kidney and respiratory insufficiency, if not treated properly and fast. It is also of special interest to differentiate between the diagnosis of ANCA-associated vasculitis and rapid progressing Glomerulonephritis (RPGM). Due to the clinically similar symptoms of anti-GBM nephritis and Wegener's granulomatosis, also in 10-38 % associated with anti-GBM antibodies, parallel testing for Pr3 and MPO antibodies is also mandatory.

AI-LFA (Autoimmune Lateral Flow Assay) GBM is a rapid assay for the qualitative determination of anti-glomerular basement membrane IgG autoantibodies (AI-LFA GBM) in human serum or plasma. AI-LFA enables the user to perform a highly sensitive and specific autoimmune test very fast and reliable.

AI-LFA GBM Specification

- Serum or plasma applicable
- Short assay time (Test results after 20 – 25 min)
- Interpretation of the results only with the LFA (Lateral Flow Assay) Reader (no visual examination)

AI-LFA GBM REF 186027 10

AI-LFA GBM Principal

AI-LFA is available as single-strip cassette plus GBM antigen solution. To perform the test the patient´s sample is transferred to the sample application point (S) of the Basis Set. Immediately afterwards the GBM antigen solution is applied. During incubation of 20-25 min the liquid is driven through the device by capillary flow. The antigen specific IgG of the sample binds specifically to the GBM antigen in the solution. The labelled antigens are retained at the test line (T) by a capture molecule. At the same time, the sIgG bound to the antigen is bound by an antibody coupled to coloured particles (conjugate) (see figure 1).

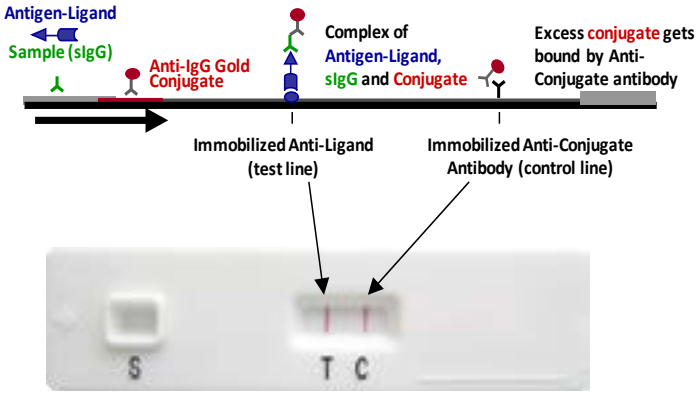

Figure 1 Test principle AI-LFA

The intensity of the colour reaction at the test line is proportional to the amount of immune complexes consisting of ligand tagged antigen, sIgG and IgG specific conjugate. The signal intensity ranges from faintly pink (low titre of anti-GBM auto-antibodies) to dark ruby (high titre of anti-GBM auto-antibodies). Access conjugate, which is not bound at the test line, forms a dark ruby control line (C) after 20-25 min of incubation.

Dr. Fooke-Achterrath Laboratorien GmbH - Habichtweg 16 - 41468 Neuss - Germany
Phone: + 49 2131 2984-0 - Fax: + 49 2131 2984-184 - email: information@fooke-labs.de

Performance data

Figure 2 shows the performance data of AI-LFA GBM using a ROC Analysis in a test setup including serum samples from 7 GBM positive patients and 32 control sera. At a Cut-off of 200 relative units (RU) the sensitivity of AI-LFA GBM was 100% in comparison to a commercially available ELISA kit. The specificity was 100%.

Pearson correlation coefficient of AI-LFA GBM vs. a commercially available ELISA kit was 0.89 (see figure 3).

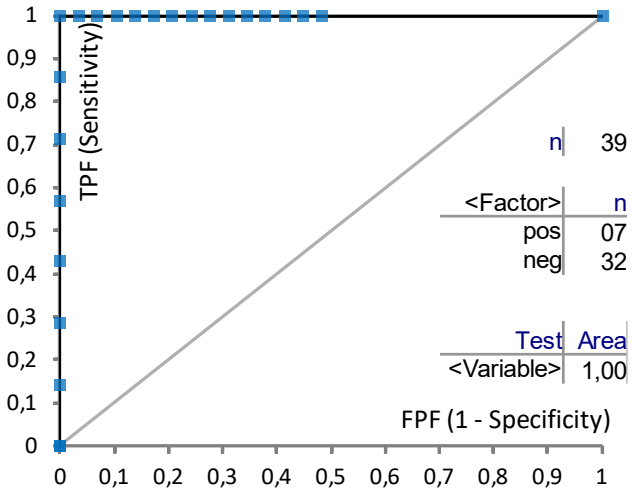

Figure 2
ROC Analysis of AI-LFA GBM vs. GBM ELISA

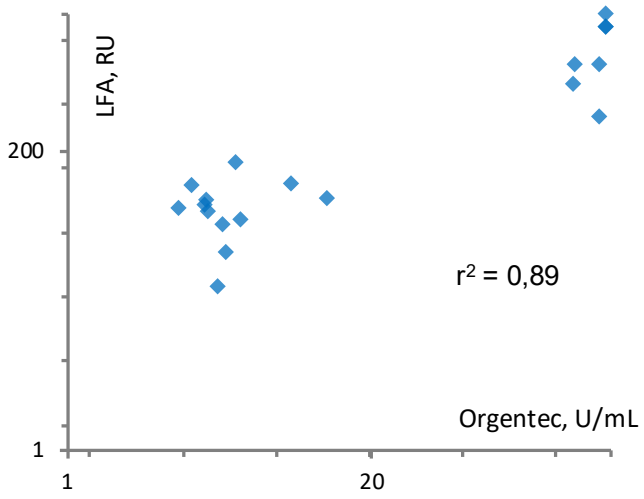

Figure 3
Pearson Correlation: AI-LFA GBM vs. GBM ELISA

Literature

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3. Roggenbuck D, Buettner T, Hoffmann L, Schmechta H, Reinhold D, Conrad K: High-sensitivity detection of autoantibodies against proteinase-3 by a novel third-generation enzyme-linked immunosorbent assay. Ann N Y Acad Sci 2009, 1173: 41-46.
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DR FOOKE

Dr. Fooke-Achterrath Laboratorien GmbH - Habichtweg 16 - 41468 Neuss - Germany
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