AI-LFA (Autoimmune Lateral Flow Assay)

Rapid assay for the qualitative determination of IgG-Autoantibodies against Proteinase 3 and Myeloperoxidase in human serum or plasma

AI-LFA Pr3 REF **186025** **AI-LFA MPO** REF **186026**

Background

Vasculitis occurs due to inflammation of blood vessel walls and exhibits many different clinical pictures, of which antineutrophil cytoplasmic antibodies (ANCA) associated small vessel vasculitis is one of the most common causes. ANCA associated vasculitis includes microscopic polyangiitis, Wegener's granulomatosis, Churg-Strauss syndrome and drug induced vasculitis. The sensitive and specific detection of Proteinase 3 (Pr3) and Myeloperoxidase (MPO) specific auto-antibodies is highly recommended even at the slightest suspicion of renal vasculitis occurring in about 80% of all Wegners granulomatosis cases. Only fast and adequate treatment can avoid the development of renal failure. Proteinase 3 is a serine protease that is mainly found in the azurophilic granula of neutrophilic granulocytes. Pr3 cleaves elastin, fibronectin and type 4 collagen. It is a component of the non-oxidative pathway of intracellular pathogen destruction. MPO is stored in azurophilic granules of the neutrophil granulocytes. It has an important role in the microbicidal activity of phagocytes. MPO produces hypochlorous acid from hydrogen peroxide and chloride anions during the neutrophil's respiratory burst.

Intended use

AI-LFA (**A**uto**i**mmune **L**ateral **F**low **A**ssay) is a rapid assay for the qualitative determination of specific IgG auto-antibodies against Proteinase 3 (AI-LFA Pr3) or Myeloperoxidase (AI-LFA MPO) in human serum or plasma. AI-LFA enables the user to perform a highly sensitive and specific autoimmune test very fast and reliable.

Principle

AI-LFA is available as single-strip cassette - plus desired antigen solution (Pr3 or MPO).
To perform the test the patient´s sample is transferred to the sample application point of the *Basis Set*. Immediately afterwards, the desired 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 its corresponding 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). 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 (see figure 1).

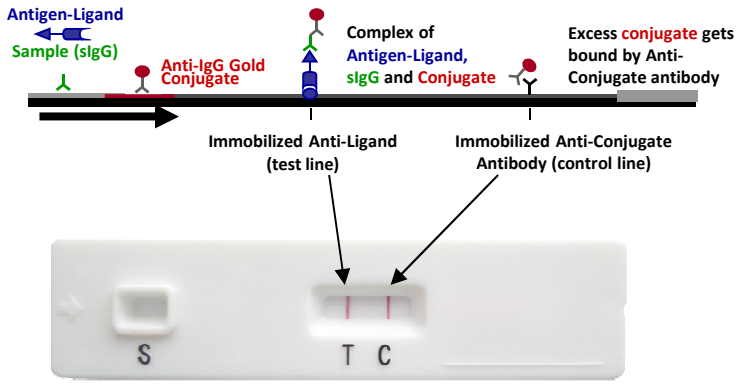

Figure 1 Principle of AI-LFA

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The signal intensity ranges from faintly pink (low titre of anti-Pr3 or anti-MPO auto-antibodies) to dark ruby (high titre of anti-Pr3 or anti-MPO 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.

Specifications

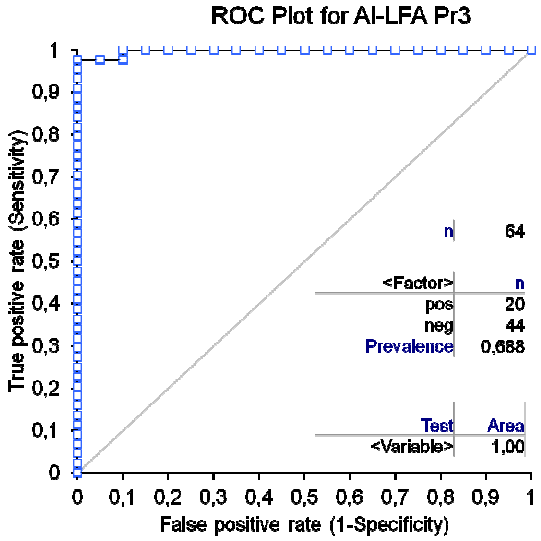
- Test results after 20 – 25 min (short assay time)
- Serum or plasma applicable
- Interpretation of the results only with the AI-LFA Reader opTrilyzer plus (no visual examination)

Performance data

Sensitivity and specificity of AI-LFA Pr3 and AI-LFA MPO were determined by ROC-Analysis in comparison to the Organtec ELISA and IFA (Immun-Fluorecence-Assay). At a Cut-off of 200 relative units (RU) the sensitivity of AI-LFA Pr3 was 100% in comparison to cANCA IFA and 97.4% in comparison to hs Organtec Pr3. The specificity was 94.7% in comparison to cANCA IFA and 93.8% in comparison to hs Organtec Pr3.
At a Cut-off of 450 RU the sensitivity as well as the specificity of AI-LFA MPO was 100% in comparison to pANCA IFA and hs Organtec MPO respectively (see figure 2).

Pearson correlation coefficient of AI-LFA vs. Orgentec ELISA was 0.87 for Pr3 and 0.83 for MPO (data not shown).

a)



b)

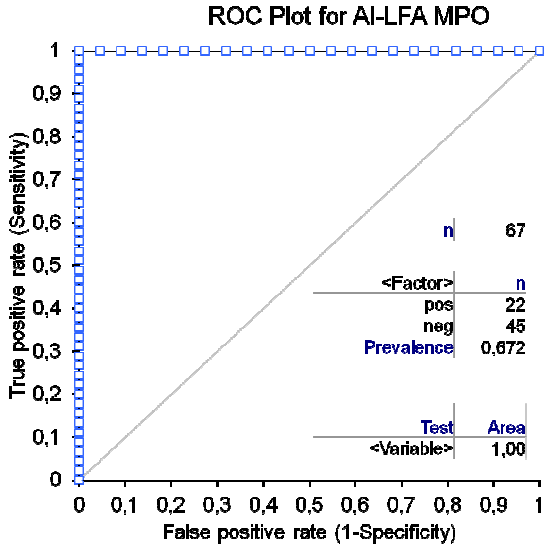


Figure 2 ROC Analysis for Pr3 (a) and MPO AI-LFA (b) vs. Orgentec

Literature

1. Conrad K, Schößler W, Hiepe F, Fritzler M: **Myeloperoxidase Antibodies.** In *Autoantibodies in Systemic Autoimmune Diseases- A Diagnostic Reference*. Edited by Conrad K, Schößler W, Hiepe F, Fritzler M. Pabst; 2007:111-113.
2. Conrad K, Schößler W, Hiepe F, Fritzler M: **Proteinase 3 Antibodies.** In *Autoantibodies in Systemic Autoimmune Diseases- A Diagnostic Reference*. Edited by Conrad K, Schößler W, Hiepe F, Fritzler M. Pabst; 2007:147-149.
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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