AI-LFA dsDNA

Rapid assay for the qualitative determination of anti-dsDNA IgG autoantibodies in human serum or plasma

For Systemic lupus erythematosus (SLE) the appearance of circulating IgG autoantibodies against defined intracellular targets including double stranded deoxyribonucleic acid (dsDNA), U1-ribonucleoproteins (RNPs), Smith antigen (Sm), histones, proliferating cell nuclear antigen (PCNA) and ribosomal phosphoproteins (Rib-P) is confirmed. Currently, more than 100 different antigens have been described as target of autoantibodies in sera of SLE patients. Anti-dsDNA antibodies are known as sensitive and specific marker for SLE. Anti-dsDNA antibodies can be detected in 20-90% of SLE patients depending on the test system, the genetic background of the patients and the setting of the patient group under investigation. The strength of the reaction of anti-dsDNA antibodies correlates with the disease activity of the patients. In rare cases, anti-dsDNA antibodies can be found in patients with related connective tissue diseases or with viral infections.

The AI-LFA dsDNA (Autoimmune Lateral Flow Assay) is a rapid assay for the qualitative determination of anti-dsDNA IgG autoantibodies in human serum or plasma. AI-LFA dsDNA enables the user to perform a specific autoimmune test very fast and reliable and offers highest sensitivity and specificity.

AI-LFA dsDNA 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 dsDNA REF 186028 10

AI-LFA dsDNA Principal

The AI-LFA dsDNA is available as single test (REF 186028). To perform the test the patient´s sample is transferred to the sample application point (S) of the Basis Set. Immediately afterwards, the anti-IgG conjugate 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 antigen at the test line. At the same time, the sIgG bound to the antigen is bound by an antibody coupled to colored particles (conjugate) (see figure 1).

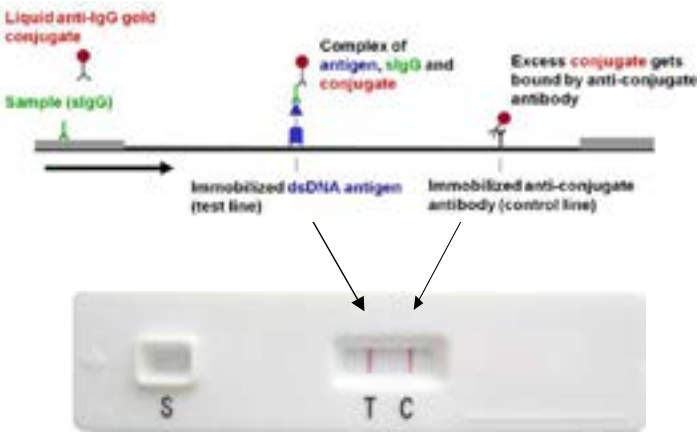

Abbildung 1 Test principle AI-LFA dsDNA

The intensity of the color reaction at the test line is proportional to the amount of immune complexes consisting of immobilized dsDNA antigen, anti-dsDNA auto-antibodies from the patient sample and IgG specific goldconjugate. The signal intensity ranges from faintly pink (low titer of anti-dsDNA autoantibodies) to dark ruby (high titer of anti-dsDNA autoantibodies).
Access conjugate, which is not bound at the test line, forms a dark ruby control line (C) after 20-25 min of incubation.

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Performance data

At an adjustment to 100% sensitivity a specificity of 100% was determined in comparison to dsDNA ELISA of Dr. Fooke Labs (see figure 2), where as a specificity of 63% was determined in comparison to an ELISA from Orgentec (see figure 3). The performance data were determined at a Cut-off of 120 relative units (RU).

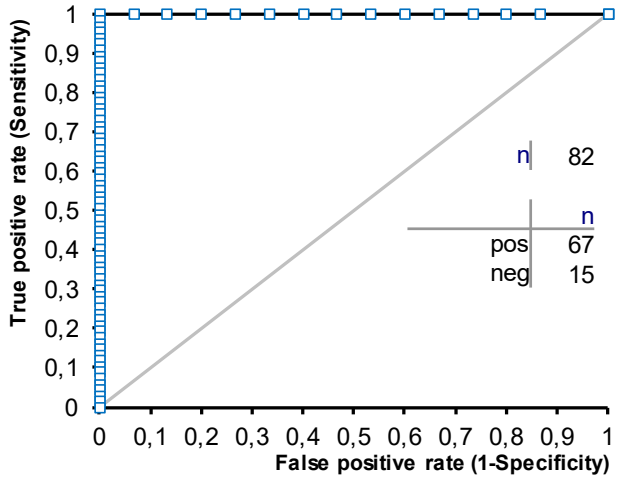

Figure 2
ROC Analysis of AI-LFA dsDNA vs. dsDNA ELISA (Dr. Fooke Labs)

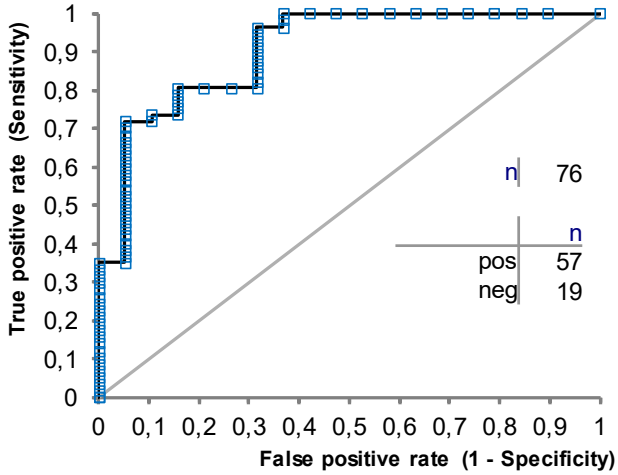

Figure 3
ROC Analysis of AI-LFA dsDNA vs. dsDNA ELISA (Orgentec)

Literature

1. Brenda B Suh-Lailam, Tyson R Chiaro, Wayne Davis K, Andrew R Wilson, Anne E Tebo: Evaluation of a high avidity anti-dsDNA IgG enzyme-linked immunosorbent assay for the diagnosis of systemic lupus erythematosus. Int J Clin Exp Pathol 2011;4(8): 748-754
2. David Launay, Jean Schmidt, Sébastien Lepers, Tristan Mirault, Marc Lambert , Xavier Kyndt, Dominique Reumaux, Alain Duhamel, Eric Hachulla, Pierre-Yves Hatron, Lionel Prin, Sylvain Dubucquoi: Comparison of the Farr radioimmunoassay, 3 commercial enzyme immunoassays and Crithidia luciliae immunofluorescence test for diagnosis and activity assessment of systemic lupus erythematosus. Clinica Chimica Acta 2010; 411: 959-964
3. Tyson R. Chiaro, Kenneth W. Davis, Andrew Wilson, Brenda Suh-Lailam, Anne E. Tebo: Significant differences in the analytic concordance between anti-dsDNA IgG antibody assays for the diagnosis of systemic lupus erythematosus—Implications for inter-laboratory testing. Clinica Chimica Acta 2011; 412: 1076-1080

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