Version 07-02/25

User's Manual

dsDNA Screen ELISA Kit

REF **DEIABL334**

Σ **96T**

RUO

This product is for research use only and is not intended for diagnostic use.

For illustrative purposes only. To perform the assay the instructions for use provided with the kit have to be used.

Creative Diagnostics

Address: 45-1 Ramsey Road, Shirley, NY 11967, USA

Tel: 1-631-624-4882 (USA) 44-161-818-6441 (Europe) **Fax: 1-631-938-8221**

Email: info@creative-diagnostics.com **Web: www.creative-diagnostics.com**

PRODUCT INFORMATION

Intended Use

dsDNA Screen ELISA is a solid phase enzyme immunoassay with human recombinant double-stranded DNA (dsDNA) for the combined quantitative and qualitative detection of IgG, IgA and IgM antibodies against dsDNA in human serum. Anti-dsDNA antibodies mainly recognize the phosphate units of the DNA, thus these autoantibodies also bind single stranded DNA (ssDNA). To ensure correct quantitation of anti-dsDNA antibodies the used antigen has been proven to be free of contamination with ssDNA.

The assay is a tool in the differential diagnosis of systemic lupus erythematosus (SLE).

General Description

dsDNA Screen ELISA is a solid phase enzyme immunoassay with human recombinant double-stranded DNA (dsDNA) for the combined quantitative detection of IgG, IgA and IgM antibodies against dsDNA in human serum. Anti-dsDNA antibodies mainly recognize the phosphat units of the DNA, thus these autoantibodies also bind single stranded DNA (ssDNA). To ensure correct quantitation of anti-dsDNA antibodies the used antigen has been proven to be free of contamination with ssDNA. Antibodies binding to DNA belong to the group of anti-nuclear antibodies (ANA) that have been observed in several autoimmune diseases. Antibodies reacting with native double-stranded (ds) DNA are regarded as being specific for systemic lupus erythematosus (SLE) and have been observed in approximately 50-80% of the patients. Antibodies against dsDNA are found during active phases of SLE. The amount of the serum concentration is positively correlated with the severity of the disease. Thus, detection of these autoantibodies is important for the diagnosis and the clinical monitoring of SLE. Consequently it has been established as 1 of the 11 ACR-criteria for the diagnosis of SLE. Most patients with SLE display IgG class antibodies against dsDNA. These autoantibodies are associated with lupus nephritis. Approximately 30% of the SLE patients develop IgA class anti-dsDNA antibodies, additionally. There have been suggestions that the presence of these IgA class anti-dsDNA antibodies may define a certain subset of SLE patients. Indeed studies demonstrated the association of this subclass with certain parameters of the disease activity, such as elevated erythrocyte sedimentation rate, or the consumption of complement component C3, as well as the clinical parameters of cutaneous vasculitis, acral necrosis and erythema. While no association was found for nephritis and arthritis. IgM class anti-dsDNA antibodies were found in 52 % of the sera from patients with SLE. In contrast to IgG and IgA class autoantibodies, the subclass IgM antibodies do not correlate with disease activity. However, a highly significant negative correlation between IgM anti-dsDNA antibodies and lupus nephritis, including its laboratory parameters was demonstrated. Therefore IgM class anti-dsDNA antibodies may indicate a subset of lupus patients being protected against the risk of developing nephritis.

Storage

2-8°C

Precision

Intra-assay		
Sample No.	Mean (U/ml)	CV (%)
1	> 300.0	2.1
2	138.0	2.4
3	26.4	4.7

Inter-assay		
Sample No.	Mean (U/ml)	CV (%)
1	463.3	2.6
2	171.6	2.3
3	58.2	4.6

Detection Range

0 - 300 U/mL, cut-off 20 U/mL

Sensitivity

1.0 U/ml.

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