



## User's Manual

# ssDNA IgA ELISA Kit



DEIABL370



96T



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.

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### Creative Diagnostics

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## PRODUCT INFORMATION

### Intended Use

ssDNA,ELISA is a solid phase enzyme immunoassay with human recombinant single-stranded DNA (ssDNA) for the quantitative and qualitative detection of IgA antibodies against ssDNA in human serum. Antibodies against ssDNA mainly recognize its basic compound, which is masked inside the helical structure of native DNA.

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

### General Description

ssDNA IgA ELISA is a solid phase enzyme immunoassay with human recombinant single-stranded DNA (ssDNA) for the quantitative detection of IgA antibodies against ssDNA in human serum. Antibodies against ssDNA mainly recognize its basic compound, which is masked inside the helical structure of native DNA. The assay is a tool in the differential diagnosis of systemic lupus erythematosus (SLE). Antibodies binding to DNA belong to the group of anti-nuclear antibodies (ANA) which occur in several autoimmune diseases. Antibodies reacting with native double-stranded (ds) DNA are regarded as being specific for systemic lupus erythematosus (SLE) and appear in approximately 50-80% of these patients. Antibodies against dsDNA are found during active phases of SLE, their serum concentration correlates with the severity of the disease. Thus, detection of these autoantibodies is important for the diagnosis and clinical monitoring of the disease and consequently has been established as 1 of the 11 ACR-criteria for the diagnosis of SLE. Antibodies to single-stranded (ss) DNA are found with a frequency of up to 87% during acute phases and 43% during inactive phases in patients with SLE. They are not specific for SLE as they may be found in other diseases like infectious mononucleosis (40%), autoimmune hepatitis (58%), acute myeloid leukemia (89%), acute lymphatic leukemia, chronic myeloid leukemia (60%) and juvenile rheumatoid arthritis (35-50%), too. SLE-like symptoms may be induced by drugs, too. As anti-ssDNA antibodies are found with a frequency of up to 50 % in patients with a drug-induced LE, the determination of antibodies against ssDNA is very helpful for the differential diagnosis.

### Storage

2-8°C

### Precision

| Intra-Assay |             |        |
|-------------|-------------|--------|
| Sample No.  | Mean (U/ml) | CV (%) |
| 1           | 127.0       | 2.6    |
| 2           | 63.0        | 1.5    |
| 3           | 42.0        | 3.1    |

| Inter-Assay |             |        |
|-------------|-------------|--------|
| Sample No.  | Mean (U/ml) | CV (%) |
| 1           | 125.0       | 3.6    |
| 2           | 60.0        | 4.1    |
| 3           | 45.0        | 3.2    |

### Detection Range



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0 - 300 U/mL, cut-off 15 U/mL

## Sensitivity

1.0 U/ml