

Autoimmunity

LIAISON® dsDNA

■ dsDNA antibody assay

Antibodies to dsDNA belong to the group of Anti-Nuclear Antibodies (ANA), which are directed against various structures of the cell nuclei. Antibodies to dsDNA are a characteristic marker in patients with active systemic autoimmune disease (SLE) and correlate with the onset of lupus nephritis. Disease activity correlates with fluctuations in antibody levels. Consequently, quantification of dsDNA autoantibodies is of paramount importance for clinical management of patients, e.g., for controlling the course of the disease, for measuring disease activity and for following up therapy outcome.

■ LIAISON® dsDNA antibody assay

The major aim of a dsDNA antibody assay is to help the clinician in the diagnosis and monitoring of the SLE patients; therefore the assay of choice must be highly specific for this disease.

DiaSorin introduces the automated LIAISON® dsDNA, an innovative chemiluminescence assay for detection of dsDNA antibodies in human serum or plasma.

Advantages of LIAISON® dsDNA over current testing technologies are expected in terms of very high diagnostic specificity, due to the use of synthetic oligonucleotide of double-stranded DNA (dsDNA).

■ Oligonucleotide dsDNA antigen

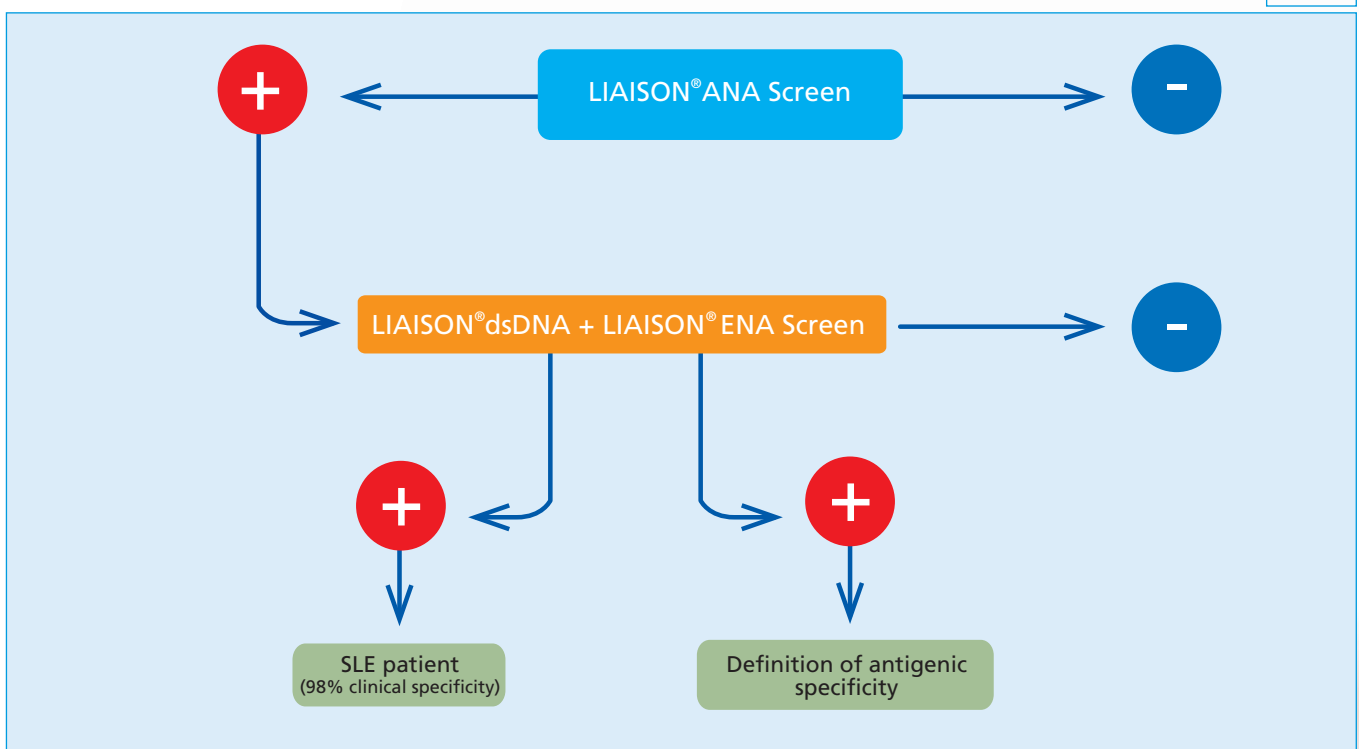
LIAISON® dsDNA uses highly purified protein-free, synthetic oligonucleotide dsDNA coated on the solid phase. This antigen allows:

- no contamination with histones and other nuclear cell proteins
- no contamination with ssDNA fragments
- optimal lot-to-lot consistency

■ Algorithm for anti-dsDNA antibody detection

dsDNA antibodies should be tested only when clinical symptoms raise the suspicion of SLE and when LIAISON® ANA Screen is positive (Fig. 1).

Fig. 1



■ Clinical performance

283 sera were selected as follows and tested with four different methods; 122 sera collected from SLE patients according to the American College of Rheumatology criteria; 101 sera collected from blood donors, and 60 sera collected from connective tissue disease (CTD) patients (16 with rheumatoid arthritis, 18 with Sjögren syndrome, 8 with systemic sclerosis, 7 with polymyositis, 7 with undifferentiated connectivitis, 4 with CREST syndrome). Four dsDNA antibody detection methods were evaluated, according to the manufacturer's instructions (Table 1).

In another external study (A.M. Rouquette et al. Immuno-Analyse et biologie spécialisée, 22, 2007 120-124) a group of 231 samples was analysed, with the following features: 153 samples from SLE patients diagnosed according to the ACR criteria (14 at first diagnosis, 139 in follow-up and/or treatment), 24 samples ENA positive but dsDNA negative with a reference method, 54 samples of patients diagnosed with other CTDs. The results show a specificity of 100%, coupled with a sensitivity of 91.5% (Table 2).

Table 1

	CLIA LIAISON®	FARR ASSAY	REFERENCE EIA ASSAY	CLIFT
<i>Cut-off</i>	20 IU/mL	7 IU/mL	30 IU/mL	1/10
Sensitivity (%)	71.3	81.1	73.8	30.6
Specificity (%)	95.0	91.3	90.7	100

Table 2

Group	N. of samples	LIAISON® positive	LIAISON® negative
SLE	153	140	13
Other CTDs	54	0	54
ENA positive, dsDNA negative	24	0	24
Total	231	140	91

■ LIAISON® dsDNA maximises the efficiency of your routine

Ease of use and quick results

- **Full automation** makes daily routine convenient and easy
- **Barcoded samples and reagents**
- **Calibration** stable for 2 weeks
- **Flexible assay protocols**
- **Continuous reagent inventory**
- **Calibrators** included
- **High throughput:** 86 results/hour
- **Time to first result:** 35 min
- **Stored master curve**
- **Small sample volume:** 20 µL