



Anti-dsDNA-NcX ELISA (IgG)



- **Test system to support the diagnosis of systemic lupus erythematosus (SLE)**
- **Suitable as a first-line test due to its increased sensitivity – no working with radioactive materials required**
- **Excellent specificity due to dsDNA complexed with nucleosomes – exceeding the current guidelines' requirements**
- **Perfect suitability for therapy monitoring shown in several publications**

Technical data

Antigen	dsDNA complexed with nucleosomes (NcX) and coupled to the solid phase
Calibration	Quantitative, in international units per milliliter (IU/ml) Calibrator 1: 800 IU/ml Calibrator 2: 100 IU/ml Calibrator 3: 10 IU/ml Recommended upper threshold of the normal range (cut-off value): 100 IU/ml
Sample dilution	Serum or plasma; 1 : 201 in sample buffer
Reagents	Ready for use, with the exception of the wash buffer (10x); colour-coded solutions, in most cases exchangeable with those in other EUROIMMUN ELISA kits
Test procedure	30 min/30 min/15 min (sample/conjugate/substrate incubation), room temperature, fully automatable
Measurement	450 nm, reference wavelength between 620 nm and 650 nm
Test kit format	96 break-off wells; kit includes all necessary reagents
Order number	EA 1572-9601 G

Clinical significance

Systemic lupus erythematosus (SLE) is an autoimmune disease belonging to the group of collagenosis. The first disease symptoms are fever and reduced physical capacity, sensitivity to sunlight and rheumatism-like disorders. The skin usually develops erythema, especially the characteristic "butterfly rash" on the face. Further frequently found symptoms are joint pains and inflammation, fatigue, limited kidney function, Raynaud's syndrome, gastrointestinal symptoms, involvement of the central nervous system and inflammation of inner organs. SLE can have a mild course or an acute inflammatory course with severe episodes and may even lead to multi-organ failure in very severe cases. The yearly incidence in Europe is around 25 to 27 new cases per 100,000 persons, with 90% of the cases being women, especially of childbearing age. Today, the five-year survival rate is around 95%.

The diagnosis of SLE is based on the EULAR/ACR criteria (EULAR = European League Against Rheumatism, ACR = American College of Rheumatology), which were last revised in 2019. SLE is considered as diagnosed when anti-nuclear antibodies (ANA) are detected in the first instance, combined with the presence of further defined clinical and immunological criteria. Due to their high specificity, anti-dsDNA antibodies are among the most important markers. Their prevalence in SLE is up to 90%, depending on the detection method and disease activity. Since their concentration correlates with the disease activity, in particular with the occurrence of lupus nephritis, the determination of the anti-dsDNA antibody titer is suited for therapy monitoring. However, SLE cannot be excluded if the anti-dsDNA result is negative. Further serologically detectable autoantibodies can be responsible for the individual clinical picture of the disease.

There is increasing evidence that the primary target antigen of the pathogenically relevant autoantibodies is not free DNA, but DNA complexed with nucleosomes. Therefore, EUROIMMUN has developed an ELISA for the detection of anti-dsDNA antibodies, whose antigen substrate consists of dsDNA which is complexed with nucleosomes (NcX) and coupled to the solid phase. Highest SLE specificity is ensured through use of a highly purified nucleosome fraction, which is free of H1, Scl-70 and other non-histone proteins. In contrast to conventional anti-dsDNA ELISAs the use of linker substances such as poly-L-lysine or protamine sulphate, which represent a potential source of unspecific reactions, is not necessary.



Linearity

The linearity of the Anti-dsDNA-NcX ELISA (IgG) was determined by performing 8 serial dilutions of different serum samples. The linear regression is $R^2 > 0.95$ for all samples. The Anti-dsDNA-NcX ELISA (IgG) is linear in at least the tested concentration range of 40 IU/ml to 757 IU/ml.

Detection limit

The lower detection limit (LoD) is defined as the mean value of an analyte-free sample plus three times the standard deviation and is the smallest clearly detectable antibody titer. The LoD of the Anti-dsDNA-NcX ELISA (IgG) is 2.6 IU/ml.

Reproducibility

The reproducibility of the test was investigated by determining the intra- and inter-assay coefficients of variation using 4 sera. The intra-assay CVs are based on 20 determinations and the inter-assay CVs on 4 determinations performed in 6 different test runs.

Intra-assay variation, n = 20		
Serum	Mean value (IU/ml)	CV (%)
1	157	4.7
2	318	2.8
3	543	2.9
4	713	3.6

Inter-assay variation, n = 4 x 6		
Serum	Mean value (IU/ml)	CV (%)
1	173	4.9
2	338	2.9
3	544	6.5
4	700	9.0

Reference range

Levels of anti-dsDNA-NcX antibodies (IgG) were determined in 400 healthy blood donors, using the EUROIMMUN ELISA. With a cut-off value of 100 RU/ml, all blood donors were anti-dsDNA-NcX negative.

Sensitivity and specificity

The sensitivity in clinically characterised SLE patients (n = 213) amounted to 60%. The specificity in a control panel (n = 760) consisting of patients with other autoimmune diseases and healthy blood donors amounted to 99%.

Patient group	n	Anti-dsDNA-NcX positive (IgG)
SLE	218	127
Sjögren's syndrome	88	1
Progressive systemic sclerosis	81	2
Rheumatoid arthritis	165	7
Polymyositis / dermatomyositis	26	0
Healthy blood donors	400	0

Literature

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