

dsDNA ELISA

REF 25005

Background

A characteristic feature of systemic autoimmune diseases such as systemic lupus erythematosus (SLE) is the occurrence of circulating antibodies against defined intra-cellular targets including double stranded desoxyribonucleic acid (dsDNA), U1-ribonucleoproteins (RNPs), Smith antigen (Sm), histones, proliferating cell nuclear antigen (PCNA) and ribosomal phosphoproteins (Rib-P). Currently, more than 100 different antigens have been described as the 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 20-70% of SLE patients depending on the test system, the genetic background of the patients and the make-up of the patient group under investigation. The titer of anti-dsDNA antibodies correlates with the disease activity of the patients. In rare cases, anti-dsDNA antibodies are found in patients with related connective tissue diseases or with viral infections.

Intended use

The dsDNA ELISA is intended for the semi-quantitative determination of antibodies specific for dsDNA. The results of the dsDNA ELISA aid to the diagnosis of SLE and related diseases.

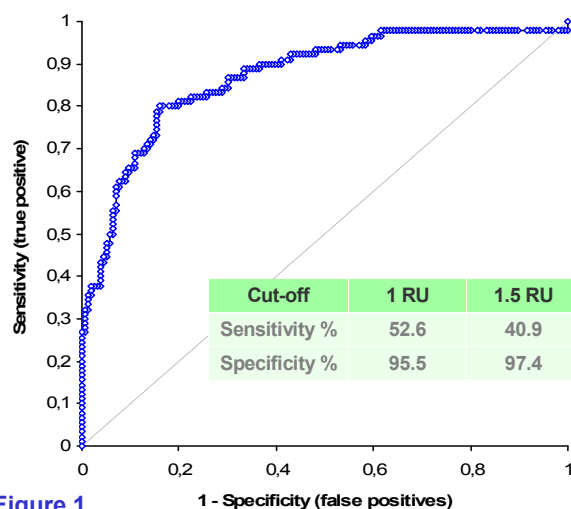


Figure 1

Receiver operating characteristics (ROC) analysis. 171 serum samples from patients with SLE and 156 controls were tested for anti-dsDNA antibodies using the dsDNA ELISA (REF: 25005). The results show a good differentiation between SLE patients and controls as revealed by an area under the curve value (AUC) of 0.87. The sensitivity and specificity of the test in this patient group was determined as 40.9 % and 97.4 %, respectively.

General features

- Highly purified plasmid antigen
- CE marked
- User-friendly
- Colored reagents
- Ready to use reagents (except washing buffer)
- Breakapart microtiter strips

Technical information

- Assay time: < 1.5 h (30 min /30 min /15 min) at RT
- 3µL serum or plasma per test
- Detection System: HRP/TMB (OD_{450 nm} /620 nm)
- Wide measuring range
- Low detection limit



Assay performance

- Good correlation to reference ELISA systems and indirect immunofluorescence on *Crithidia luciliae* substrate
- Excellent “lot to lot” correlation $R^2 > 0.95$
- Low intra- and inter-assay variation $CV\% < 10$
- Excellent linearity over the entire range

ID	Target	RU	Interpretation
CDC 1	DNA	6.7	positive
CDC 2	SS-B/La	0.4	negative
CDC 3	RNP/Sm, SS-A/Ro, SS-B (La)	0.3	negative
CDC 4	U-1 RNP	0.4	negative
CDC 5	Sm	0.7	negative
CDC 6	Fibrillarin	0.2	negative
CDC 7	SS-A/Ro	0.6	negative
CDC 8	Centromere	0.4	negative
CDC 9	Scl-70	0.7	negative
CDC 10	Jo-1	0.2	negative
CDC 11	PM/Scl (PM 1)	0.4	negative
CDC 12	Rib-P	0.2	negative

Figure 2
Results of the CDC ANA reference sera. 12 reference serum samples, available from the “Center for Disease Control and Prevention (CDC)” were tested in the dsDNA ELISA (REF:25005). Only the anti-dsDNA positive sample (CDC 1) was found to be positive.

Table 1 Anti-dsDNA reactivity in different disease groups

	No. (%) of anti-dsDNA positive sera
SLE (n=171)	70 (40.9)
Rheumatic disease controls (84)	4 (4.7)
RA (22)	2 (2.3)
MCTD (7)	2 (2.3)
SSc (2)	0 (0)
DM (2)	0 (0)
UCTD (7)	0 (0)
Other rheumatic diseases (37)	0 (0)
Healthy individuals (72)	0 (0)

		dsDNA ELISA (25005)		
		neg	pos	
Reference	neg	27	5	32
	pos	6	29	35
		33	34	67

Figure 3
Agreement to reference ELISA. 67 serum samples from patients with SLE tested in the dsDNA ELISA (REF:25005) and in a validated reference method (CLIFT) demonstrated a good agreement (83.6%) between the two assays.

Literature

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