



La (SS-B) ELISA

REF 25008

Background

Circulating antibodies to intra-cellular structures especially to nuclear antigens represent a characteristic feature of systemic autoimmune diseases. One of these antigens, termed as La (SS-B), has first been described in the serum of a patient with Sjögren Syndrome (SjS). Antibodies to the 48 kDa (SS-B) antigen can also occur in patients with systemic lupus erythematosus (SLE), mixed connective tissue disease (MCTD), or systemic sclerosis (SSc). Anti-La (SS-B) antibodies frequently occur together with anti-Ro (SS-A) antibodies. Moreover, anti-La antibodies seem to play an important role in the context of neonatal lupus and congenital heart block in which certain epitopes are associated with complications during pregnancy.

Intended use

The La (SS-B) ELISA is intended for the semi-quantitative determination of antibodies specific for the La protein. The results of the La ELISA aid to the diagnosis of SjS and related systemic autoimmune diseases.

General features

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

Technical information

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

ID	Target	RU	Interpretation
CDC 1	DNA, Sm	0.1	negative
CDC 2	SS-B/La	3.5	positive
CDC 3	RNP/Sm, SS-A/Ro, SS-B/La	2.7	positive
CDC 4	U-1 RNP	0.1	negative
CDC 5	Sm	0.3	negative
CDC 6	Fibrillarin	0.5	negative
CDC 7	SS-A/Ro	0.1	negative
CDC 8	Centromere	0.1	negative
CDC 9	Scl-70	0.2	negative
CDC 10	Jo-1	0.1	negative
CDC 11	PM/Scl (PM 1)	0.1	negative
CDC 12	Rib-P	0.1	negative

Figure 1

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 LA (SS-B) ELISA (REF: 25008). Sample CDC 2 and CDC 3 were positive for anti-La antibodies.



Assay performance

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

ID	Diagnosis	RU	Interpretation	No. of competitors with positive result for La(SS-B)
AMLI 1	HD	0.3	negative	0
AMLI 2	SLE	0.0	negative	0
AMLI 3	MCTD	0.0	negative	0
AMLI 4	SjS	0.1	negative	0
AMLI 5	SjS	2.5	positive	22/22
AMLI 6	Scl	0.0	negative	0
AMLI 7	PM	0.1	negative	0
AMLI 8	CREST	0.1	negative	0
AMLI 9	SLE	1.7	positive	13/22
AMLI 10	HD	0.2	negative	0

HD = healthy donor; SLE = systemic lupus erythematosus; MCTD = mixed connective tissue disease; SjS = Sjögren Syndrome; Scl = systemic sclerosis; CREST = (calcinosis, Raynaud phenomenon, esophageal dysmotility, sclerodactyly, and telangiectasia); PM = Polymyositis

Figure 2

Results of the AMLI reference sera. 10 reference serum samples, available from the Association of Medical Laboratory Immunologists (AMLI) were tested in the LA ELISA (REF: 25008). Samples AMLI 5 and AMLI 9 were tested positive for anti-La-antibodies in concordance to the findings of 22 reference laboratories.

Table 1 Prevalence of anti-La (SS-B) in different disease groups and healthy donors

Group	% pos literature	% pos La ELISA (REF: 25008)
SjS	50 - 70	61.4
SLE	20 - 35	23.2
SSc(Scl)	<10	4
HD	0	0

HD = healthy donor; SLE = systemic lupus erythematosus; SjS = Sjögren Syndrome; SSc (Scl) = systemic sclerosis

La ELISA (25008)				
Reference		neg	pos	
	neg	62	5	67
	pos	1	8	9
		63	13	76

Figure 3

Agreement to reference method. 76 serum samples from patients with SLE tested in the La ELISA (REF: 25008) and in a validated reference ELISA demonstrated a good agreement (92.1%) between the two assays.

Literature

1. Tan EM: **Antinuclear antibodies: diagnostic markers for autoimmune diseases and probes for cell biology.** *Adv Immunol* 1989, **44**:93-151.
2. James K, Carpenter AB, Cook L, Marchand R, and Nakamura RM for the Association of Medical Laboratory Immunologists Standards Committee: **Development of the Antinuclear and Anti-cytoplasmic Antibody Consensus Panel by the Association of Medical Laboratory Immunologists.** *Clin Diagn Lab Immunol* 2000, **7**:436–443.
3. Conrad K, Schößler W, Hiepe F: **Autoantibodies in Systemic Autoimmune Diseases** Pabst Science Publishers Lengerich, Berlin, Riga, Rom, Wien, Zagreb.

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