La (SS-B) ELISA

The La ELISA contributes to the diagnosis of the Sjögren Syndrome (SjS) and related systemic autoimmune diseases

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.

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.

La ELISA Specifications

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

La ELISA REF 25008 96

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 R2 > 0.95
- Low intra- and inter-assay variation CV% < 10
- Excellent linearity over the entire range

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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)		
		neg	pos	
Reference	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.
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