Sm ELISA

The Sm ELISA contributes to the diagnosis of systemic lupus erythematosus (SLE) and related systemic autoimmune diseases

Circulating antibodies to intra-cellular structures especially to nuclear antigens represent a characteristic feature of systemic autoimmune diseases. Antibodies to the Sm complex are regarded as highly specific markers for systemic lupus erythematosus (SLE) where they can be detected in 5-30% of the patients. Due to the high disease specificity anti-Sm antibodies have been included as one of the American College of Rheumatology (ARC) disease criteria for the diagnosis of SLE. The Sm complex is a multiprotein complex consisting of 9 known ribonucleo-proteins (RNP). Since SmBB´ and U1-RNPs share cross-reactive epitopes, SmD has been proven to be the most disease specific marker autoantigen. As SmD proteins contain the modified amino acid dimethylarginine (DMA) which cannot be produced in a recombinant format, native antigens or synthetic peptides should be preferred for the detection of anti-Sm antibodies.

The Sm ELISA is intended for the semi-quantitative determination of antibodies specific for the Sm protein complex. The results of the Sm ELISA aid to the diagnosis of SLE and related systemic autoimmune diseases.

Sm ELISA REF 25010 96

ID	Target	RU	Interpretation
CDC 1	DNA, Sm	1.9	positive
CDC 2	SS-B/La	0.3	negative
CDC 3	RNP/Sm, SS-A/Ro, SS-B/La	1.6	positive
CDC 4	U-1 RNP	0.4	negative
CDC 5	Sm	6.0	positive
CDC 6	Fibrillarin	0.3	negative
CDC 7	SS-A/Ro	0.3	negative
CDC 8	Centromere	0.3	negative
CDC 9	Scl-70	0.3	negative
CDC 10	Jo-1	0.1	negative
CDC 11	PM/Scl (PM 1)	0.4	negative
CDC 12	Rib-P	0.3	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 Sm ELISA (REF: 25010). Sample CDC1, CDC 3, CDC 5 were positive for anti-Sm antibodies.

Sm ELISA Specifications

- Highly purified native antigen containing symmetrical dimethylarginine
- 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

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

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ID	Diagnosis	RU	Interpretation	No. of competitors with positive result for Sm
AMLI 1	HD	0.1	negative	0
AMLI 2	SLE	3.1	positive	21/21
AMLI 3	MCTD	0.1	negative	4/21
AMLI 4	SjS	0.1	negative	0
AMLI 5	SjS	0.2	negative	0
AMLI 6	Scl	0.1	negative	0
AMLI 7	PM	0.1	negative	0
AMLI 8	CREST	0.1	negative	1/?
AMLI 9	SLE	0.3	negative	0
AMLI 10	HD	0.1	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 = Polymoysitis

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 Sm ELISA (REF: 25010). Only sample AMLI 2 was found to be positive. The results show a good agreement to the findings of 21 reference laboratories.

Table 1
Prevalence of anti-Sm in different disease groups and healthy donors

	No. (%) pos	Max	Mean
SLE (n=89)	10 (11.2)	6.8	0.9
Controls (n=165)	2 (1.2)	2.0	1.1
RA (n=23)	1 (4.4)	2.0	0.5
Other AID (n=63)	1 (1.6)	1.8	0.5
HD (n=79)	0 (0)	0.5	1.1

HD = healthy donor; SLE = systemic lupus erythematosus;
RA = rheumatoid arthritis; AID = autoimmune diseases

Sm ELISA (25010)				
		neg	pos	
Reference	neg	48	4	52
	pos	1	7	8
		49	11	60

Figure 3
Agreement to reference method. 60 serum samples from patients with connective tissue disease tested in the Sm ELISA (REF: 25010) and in a validated reference line immunoassay (LIA) for anti-SmD antibodies demonstrated a good agreement (91,7 %) between the two assays

Literature

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