Sm ELISA

REF 25010

Background

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.

Intended use

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.

General features

- Highly purified native antigen containing symmetrical dimethylarginine
- 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	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.

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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 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 = 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 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)				
Reference		neg	pos	
	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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