



# RNP/Sm ELISA

**REF** 25011

## Background

Circulating antibodies to intra-cellular structures especially to nuclear antigens represent a characteristic feature of systemic autoimmune diseases. Antibodies to the ribonucleoprotein (RNP) complex in high titers are considered as a specific marker for mixed connective tissue disease (MCTD) found in 40-90% of MCTD patients. Due to the high disease specificity of anti-RNP/Sm they have been included as one of the disease criteria for the diagnosis of MCTD. The RNP/Sm complex consists of 3 known U1-specific RNPs (U1-68 kDa, U1-A, U1-C) and 9 Sm polypeptides (SmB, SmB', SmN, SmD1, SmD2, SmD3, SmE, SmF, SmG). Apart from patients with MCTD anti-RNP/Sm antibodies can also be detected in samples from patients with related autoimmune disorders such as systemic lupus erythematosus (SLE) and systemic sclerosis (SSc).

## Intended use

The RNP/Sm ELISA is intended for the semi-quantitative determination of antibodies specific for the RNP/Sm protein complex. The results of the RNP/Sm ELISA aid to the diagnosis of MCTD and related autoimmune disorders.

## General features

- Highly purified, native 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<sub>450 nm</sub> /620 nm)
- Wide measuring range
- Low detection limit

ID	Target	RU	Interpretation
CDC 1	DNA	3.0	positive
CDC 2	SS-B/La	0.3	negative
CDC 3	RNP/Sm, SS-A/Ro, SS-B (La)	7.3	positive
CDC 4	U-1 RNP	7.5	positive
CDC 5	Sm	7.8	positive
CDC 6	Fibrillarin	0.5	negative
CDC 7	SS-A/Ro	0.2	negative
CDC 8	Centromere	0.2	negative
CDC 9	Scl-70	0.2	negative
CDC 10	Jo-1	0.1	negative
CDC 11	PM/Scl (PM 1)	0.3	negative
CDC 12	Rib-P	0.2	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 RNP/Sm ELISA (REF: 25011). Sample CDC 1, CDC 3, CDC 4 and CDC 5 were positive for anti-RNP/Sm 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	Diagnose	RU	Interpretation	No. of competitors with positive results for RNP/Sm
AML1 1	HD	0.2	negative	0
AML1 2	SLE	6.8	positive	21/21
AML1 3	MCTD	1.9	positive	20/21
AML1 4	SjS	0.2	negative	0
AML1 5	SjS	0.2	negative	0
AML1 6	Scl	0.2	negative	0
AML1 7	PM	0.2	negative	0
AML1 8	CREST	0.2	negative	0
AML1 9	SLE	0.4	negative	0
AML1 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 (AML1) were tested in the RNP/Sm ELISA (REF: 25011). Samples AML1 2 and AML1 3 were tested positive in concordance to the findings of 21 reference laboratories.

**Table 1** Prevalence of anti-RNP/Sm in different disease groups and healthy donors according to the literature

Group	% pos literature	% pos RNP/Sm ELISA (REF: 25011)
SLE	20 - 40	35.1
SSc (Scl)	2 - 14	6
SjS	< 10	8.6
Myositis	4 - 17	7
HD	0	0

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

RNP/Sm ELISA (2501 1)				
Reference		neg	pos	
	neg	0	0	0
	pos	3*	62	65
		3	62	65

**Figure 3**

Agreement to reference method. 65 serum samples from patients with connective tissue disease tested in the RNP/Sm ELISA (REF: 25011) and in a validated reference ELISA demonstrated a good agreement (96.0%) between the two assays.

\*One sample was borderline by RNP/Sm ELISA (RU=1.0)

## Literature

1. Tan EM: **Antinuclear antibodies: diagnostic markers for autoimmune diseases and probes for cell biology.** *Adv Immunol* 1989, **44**:93-151.
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3. Mahler M, Waka A, Hiepe F, Fritzler MJ: **Effect of dsDNA binding to SmD derived peptides on the clinical accuracy in the diagnosis of systemic lupus erythematosus.** *Arthritis Res Ther* 2007, **9**:R68.
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