CENP ELISA

REF 25004

Background

Circulating autoantibodies (aab) to intracellular structures such as Scl-70 (Topoisomerase I; Topo I), Fibrillarin, the human exosome (PM/Scl complex) and the centromere proteins (CENP) represent a characteristic feature of systemic sclerosis (SSc). Anti-centromere aab are found in 20-50 % of patients with SSc depending on the detection system and on the selection of the patient cohort, but can also be observed in lower frequency in other disease conditions such as systemic lupus erythematosus (SLE) and rheumatoid arthritis (RA). Several studies showed an association between anti-CENP antibodies and the CREST syndrome (*calcinosis, Raynaud phenomenon, esophageal dysmotility, sclerodactyly and telangiectasia*). Moreover, patients with anti-CENP aab have been reported to have a better prognosis compared to patients with other SSc related aab.

Intended use

The CENP ELISA is intended for the semi-quantitative determination of aab specific for the CENP-B protein for differential diagnosis in the CREST syndrome. The results of the CENP ELISA aid to the diagnosis of systemic sclerosis. Due to the fact that anti-CENP-B reactivity correlates with a mild disease progression anti-CENP aab might be of prognostic value.

General features

- Recombinant CENP-B 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	0.3	negative
CDC 2	SS-B/La	0.3	negative
CDC 3	RNP/Sm, SS-A/Ro, SS-B (La)	0.3	negative
CDC 4	U-1 RNP	0.3	negative
CDC 5	Sm	0.7	negative
CDC 6	Fibrillarin	0.2	negative
CDC 7	SS-A/Ro	0.2	negative
CDC 8	Centromere	4.5	positive
CDC 9	Scl-70	0.3	negative
CDC 10	Jo-1	0.1	negative
CDC 11	PM/Scl (PM 1)	0.3	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 CENP ELISA (REF: 25004). Only the anti-CENP positive sample (CDC 8) was found to be positive.

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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
AMLI 1	HD	0.1	negative	0
AMLI 2	SLE	0.0	negative	0
AMLI 3	MCTD	0.0	negative	0
AMLI 4	SjS	0.0	negative	0
AMLI 5	SjS	0.1	negative	0
AMLI 6	Scl	0.0	negative	0
AMLI 7	PM	0.1	negative	0
AMLI 8	CREST	4.3	positive	8/8
AMLI 9	SLE	0.2	negative	0
AMLI 10	HD	0.1	negative	0

HD = healthy donor; SLE = systemic lupus erythrematosus; 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 Association of Medical Laboratory Immunologists (AMLI) reference sera. 10 reference serum samples, available from the AMLI were tested in the CENP ELISA (REF: 25004). Only the anti-CENP positive sample (AMLI 8) was found to be positive (4.3 RU). All other samples were found below 0.3 RU. The results are in good agreement to other immunoassays for the detection of anti-centromere antibodies.

Table 1
Prevalence of anti-CENP antibodies in systemic sclerosis and controls

	No. (%) > 1.0 RU	No. (%) > 1.5 RU	Mean/Median RU	Min/Max RU
SSc (n=131)	53 (40.5)	49 (37.4)	2.77/0.47	0.2/9.6
SLE (n=109)	21 (19.3)	6 (5.5)	0.81/0.66	0.2/6.3
RA (n=15)	0 (0.0)	0 (0.0)	0.51/0.49	0.3/0.9
Other SARD (n=10)	1 (10.0)	1 (10.0)	0.71/0.61	0.3/1.6
Controls all (n=134)	22 (16.4)	7 (5.2)	0.76/0.61	0.2/6.3

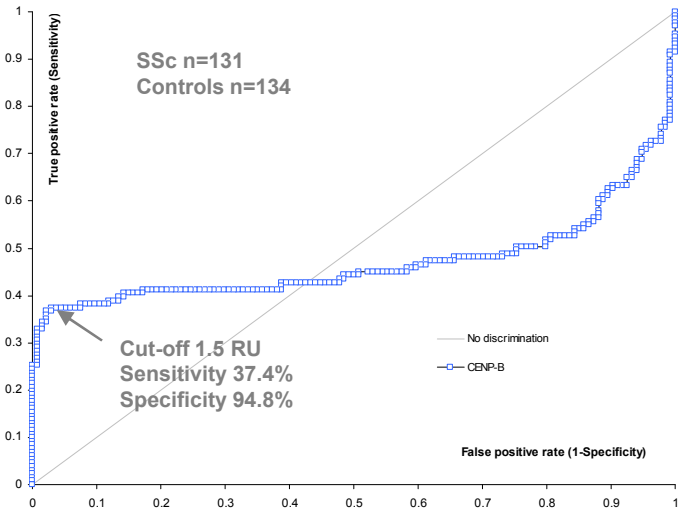

Figure 3
Receiver operating characteristics (ROC) analysis. 131 serum samples from patients with SSc and 134 controls were tested for anti-CENP antibodies using the CENP ELISA (REF: 25004). The results show a good differentiation between SSc patients and controls. The sensitivity and specificity of the test in this patient group was determined as 37.4% and 94.8%, respectively.

Literature

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