Scl-70 ELISA

The Scl-70 ELISA contributes to the diagnosis of systemic sclerosis (SSc)

Circulating antibodies to intra-cellular structures especially to nuclear antigens represent a characteristic feature of systemic autoimmune diseases. Anti-bodies to Scl-70/Topoisomerase I (topo-I) represent a highly specific marker for the diagnosis of systemic sclerosis (SSc) also known as scleroderma. Anti-Scl-70 antibodies are found with high prevalence of up to 70% in patients with SSc with diffuse skin manifestations and are associated with severe disease progression. The correlation between disease activity and severity and the antibody titer determined by ELISA is discussed and remains a matter of further research.

The Scl-70 ELISA is intended for the semi-quantitative determination of anti-Scl-70 antibodies. The results of the Scl-70 ELISA aid to the diagnosis of systemic sclerosis. Based on the association between anti-Scl-70 antibodies and diffuse skin manifestation and severe disease progression anti-Scl-70 may be used as prognostic marker.

Scl-70 ELISA REF 25003 96

ID	Target	ELISA (RU)	Interpretation
CDC 1	DNA	0.6	negative
CDC 2	SS-B/La	0.4	negative
CDC 3	RNP/Sm, SS-A/Ro, SS-B (La)	0.4	negative
CDC 4	U-1 RNP	0.3	negative
CDC 5	Sm	0.5	negative
CDC 6	Fibrillarin	0.5	negative
CDC 7	SS-A/Ro	0.3	negative
CDC 8	Centromere	0.2	negative
CDC 9	Scl-70	4.2	positive
CDC 10	Jo-1	0.2	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 Scl-70 ELISA (REF: 25003). Only the anti-Scl-70 positive sample was found to be positive.

Scl-70 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

Assay performance

- Good correlation to reference assay (LIA) systems
- Excellent "lot to lot" correlation R2 > 0.95
- Low intra- and inter-assay variation CV% < 8
- Excellent linearity over the entire range

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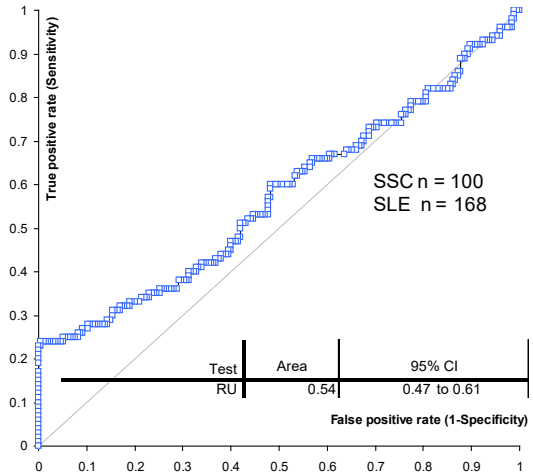
a)



b)

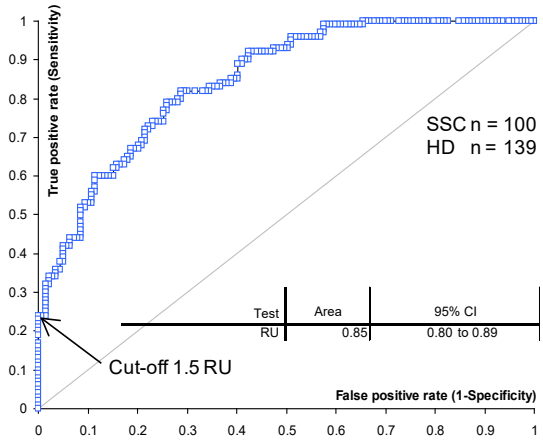


Figure 2
Receiver operating characteristics (ROC) analysis. ROC Analysis was performed with a.) results of SSc sera vs. results of SLE patients and b.) healthy donors (HD). (Area = area under the curve; n = number of sera.)

kappa = 0.97 (CI = 0.92 to 1.03); p < 0.0001

	ELISA		
LIA	pos	neg	Total
pos	**23**	**0**	23
neg	**1**	**76**	77
Total	24	76	100

kappa = 0.85 (CI = 0.73 to 0.98); p < 0.0001

	ELISA		
ALBIA	pos	neg	Total
pos	**19**	**0**	19
neg	**5**	**76**	81
Total	24	76	100

kappa = 0.88 (CI = 0.77 to 0.99); p < 0.0001

	LIA		
ALBIA	pos	neg	Total
pos	**19**	**0**	19
neg	**4**	**77**	81
Total	23	77	100

Figure 3
Agreement to other methods. 100 serum samples from patients with scleroderma were tested in the Scl-70 ELISA (REF: 25003) and in two reference methods demonstrating a good agreement between all of the assays (Results based on a cut-off of 1.5 RU).
ALBIA = Addressable laser bead assay
CI = Confidence interval
LIA = Line immunoassay

Literature

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