



Sci-70 ELISA

REF 25003

Background

Circulating antibodies to intra-cellular structures especially to nuclear antigens represent a characteristic feature of systemic autoimmune diseases. Antibodies to Sci-70/Topoisomerase I (topo-I) represent a highly specific marker for the diagnosis of systemic sclerosis (SSc) also known as scleroderma. Anti-Sci-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.

Intended use

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

General features

- Recombinant 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	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	Sci-70	4.2	positive
CDC 10	Jo-1	0.2	negative
CDC 11	PM/Sci (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 Sci-70 ELISA (REF: 25003). Only the anti-Sci-70 positive sample was found to be positive.



Assay performance

- Good correlation to reference assay (LIA) systems
- Excellent “lot to lot” correlation $R^2 > 0.95$
- Low intra- and inter-assay variation $CV\% < 8$
- Excellent linearity over the entire range

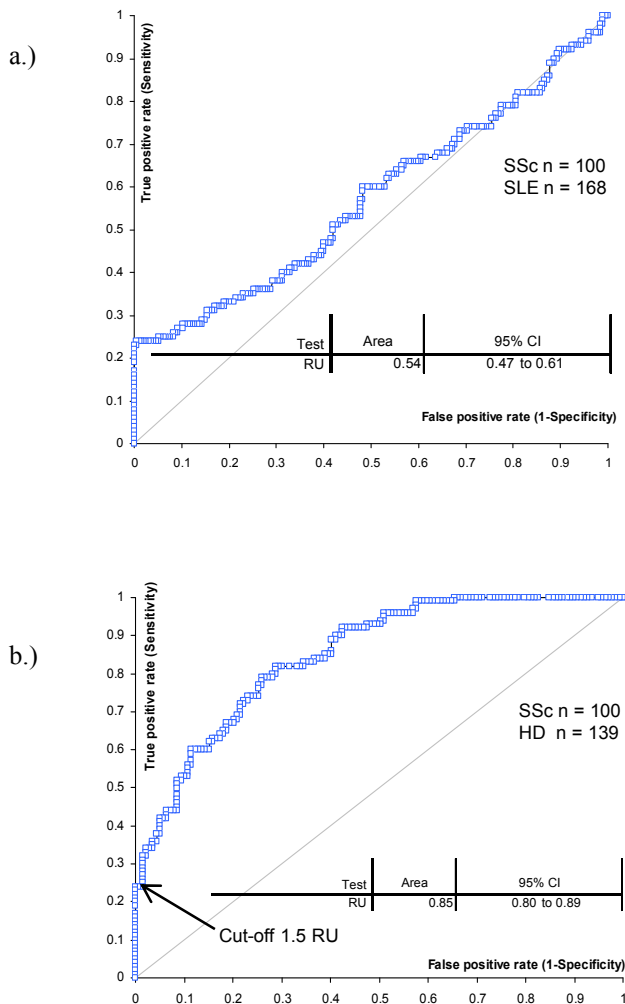


Figure 2

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); $p < 0.0001$

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

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

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

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

ALBIA	LIA		Total
	pos	neg	
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 Sci-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

1. Tan EM: **Antinuclear antibodies: diagnostic markers and clues to the basis of systemic autoimmunity.** *Pediatr Infect Dis J* 1988, **7**: S3-S9.
2. Jarzabek-Chorzelska M, Blaszczyk M, Jablonska S, Chorzelski T, Kumar V, Beutner EH: **Sci 70 antibody- a specific marker of systemic sclerosis.** *Br J Dermatol* 1986, **115**: 393-401.
3. Spencer-Green G, Alter D, Welch HG: **Test performance in systemic sclerosis: anti-centromere and anti-Sci-70 antibodies.** *Am J Med* 1997, **103**: 242-248.
4. Ho K, Reveille J: **The clinical relevance of autoantibodies in scleroderma.** *Arthritis Res Ther* 2003, **5**: 80-93.
5. Mahler M, Silverman ED, Schulte-Pelkum J, Fritzler MJ: **Anti-Sci-70 (topo-I) antibodies in SLE: Myth or reality?** *Autoimmun Rev* 2010, **9**: 756-760.

2011-05