



PM1-Alpha ELISA

REF

25001

Background

Circulating antibodies to intra-cellular structures especially to nuclear antigens represents a characteristic feature of systemic autoimmune diseases. Systemic sclerosis (SSc, Scl) for example is characterized by antibodies to topoisomerase I known as Scl-70. Anti-PM/Scl antibodies represent a specific serological marker for a subset of patients with Scl, polymyositis (PM) and especially with the PM/Scl overlap syndrome. Anti-PM/Scl reactivity is found in 24% of PM/Scl patients and in 3-10% of Scl and 8% of PM patients. The majority of anti-PM/Scl antibodies are directed against an alpha helical epitope located at amino acid 231-245 of PM/Scl-100 termed as PM1-Alpha. Recently obtained data clearly showed that a PM1-Alpha based ELISA is a reliable tool to detect anti-PM/Scl antibodies.

Intended use

The PM1-Alpha ELISA is intended for the semi-quantitative determination of anti-PM1-Alpha antibodies contributing to a better diagnosis of the PM/Scl overlap syndrome. Since patients with antibodies to PM/Scl tend to have a milder disease progression and a higher survival rate compared to patients with anti-Scl-70 the detection of anti-PM1-Alpha antibodies is important for the prognosis of patients with systemic sclerosis.

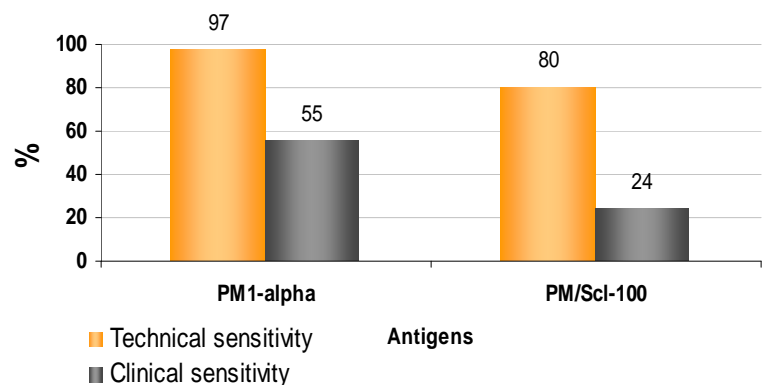


Figure 1

Technical and clinical sensitivity in % of PM1-Alpha peptide and recombinant PM/Scl-100. Anti-PM/Scl sera preselected based on Immunofluorescence and Immunoblot were tested for anti-PM/Scl antibodies using the PM1-Alpha peptide and the recombinant PM/Scl-100 protein. Moreover, samples from PM/Scl patients and various controls were assayed with the new PM1-Alpha ELISA (REF: 25001). The clinical sensitivity for the recombinant protein was taken from the literature.

General features

- Synthetic peptide 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



Assay performance

- Excellent clinical (55%) and technical (97%) sensitivity
- Good correlation to ELISA systems with recombinant or native proteins
- Excellent "lot to lot" correlation $R^2 > 0.95$
- Low intra- and inter-assay variation
- Excellent linearity over the entire range

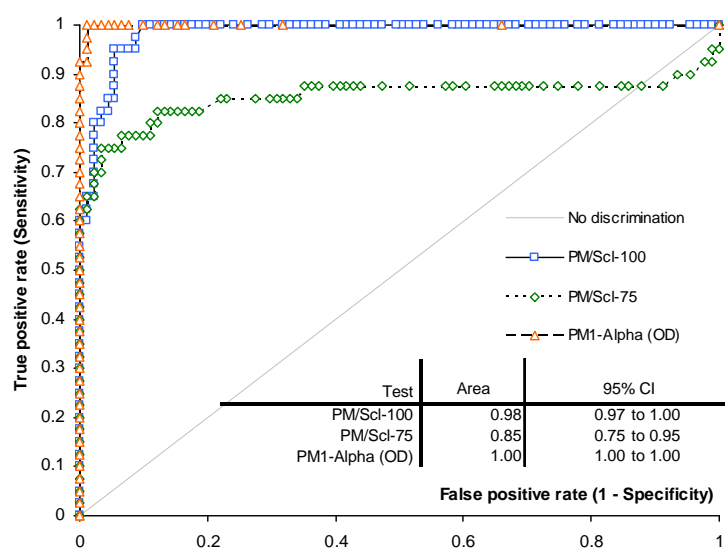


Figure 2

Receiver operating characteristics (ROC) analysis. 40 sera with Anti-PM/ScI reactivity identified by indirect immunofluorescence on HEp-2 cells and confirmed by line immunoassay were tested in ELISA with recombinant PM/ScI-100, PM/ScI-75 and PM1-Alpha. Comparative ROC analysis shows good (PM/ScI-75) to excellent discrimination (PM1-Alpha) between predefined PM/ScI positive and negative samples (Mahler et al. 2008).

Table 1

Reactivity of PM/ScI sera and controls in the PM1-Alpha ELISA

	No. (%) of anti-PM1- α positive sera	Mean value / SD	Top value
PM/ScI (n=40)	22 (55)	3.1 / 3.2	11.6
Rheumatic disease controls (369)			
PM (40)	16 (4.3)	0.6 / 0.9	7.7
ScI (130)	3 (7.5)	1.0 / 1.1	7.4
RA (69)	11 (8.5)	0.7 / 1.3	7.5
MCTD (6)	0 (0)	0.3 / 0.2	1.1
UCTD (10)	0 (0)	0.4 / 0.1	0.6
SLE (114)	0 (0)	0.3 / 0.0	0.4
Other rheumatic diseases (8)	3 (2.6)	0.5 / 0.7	7.7
HCV (48)	0 (0)	0.3 / 0.1	0.6
HCV (48)	2 (4.2)	0.5 / 0.5	2.6
Organ specific disorders (n=23)			
HT (11)	0 (0)	0.4 / 0.2	0.8
GD (12)	0 (0)	0.3 / 0.2	0.8
GD (12)	0 (0)	0.4 / 0.2	0.8
Healthy individuals (4)	0 (0)	0.6 / 0.2	0.7

Mahler et al. 2005

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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6. Mahler M, Mierau R, Humbel R and Fritzler MJ. **Anti-PM1-Alpha antibodies: Analytical evaluation in two centers.** 6th Congress on autoimmunity held in Porto, Portugal 2008