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 antibodies the detection of anti-PM1-Alpha antibodies is important for the prognosis of patients with systemic sclerosis.

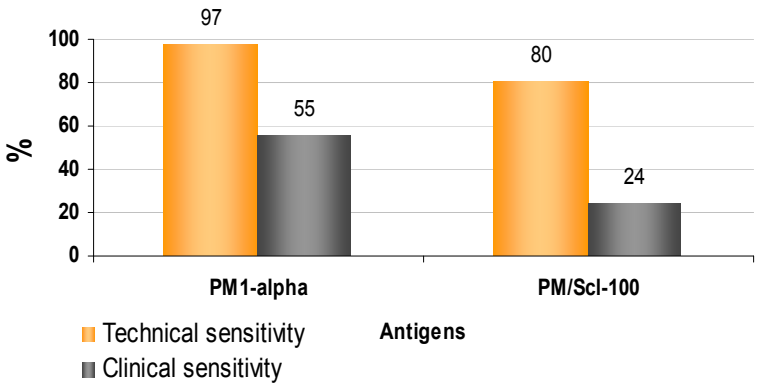

Figure 1
Technical and clinical sensitivity in % of PM1-Alpha peptide and recombinant PM/Scl-100. Anti-PM/Scl sera preselected based on Immunofluorescence and Immunoblot were tested for anti-PM/Scl antibodies using the PM1-Alpha peptide and the recombinant PM/Scl-100 protein. Moreover, samples from PM/Scl 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

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Table 1

Meta-analysis of anti-PM1-Alpha autoantibodies in disease cohorts (Mahler M, Fritzler MJ 2009).

	Mahler et al. [27]	Mahler et al. [34]	Mahler et al. [16]	Santiago et al. [40]	Mahler et al. unpublished	All
PM/Scl	22/40 (55.0)	na	na	na	na	22/40 (55.0)
SSc	27/205 (13.2)	23/495 (7.1)	na	17/242 (7.0)	64/719 (8.9)	131/1661 (7.9)
lSSc	na	na	14/204 (6.9)	na	na	14/204 (6.9)
dSSc	na	na	4/41 (9.8)	na	na	4/41 (9.8)
PM	3/40 (7.5)	na	na	na	na	3/40 (7.5)
DM	na	na	na	na	na	na
SLE	3/114 (2.6)	na	21/300 (0.7)	na	na	5/414 (1.2)
RA	0/69 (0.0)	na	na	na	na	0/69 (0.0)
MCTD	0/6 (0.0)	na	na	na	na	0/6 (0.0)
UCTD	0/10 (0.0)	na	na	na	na	0/10 (0.0)
HCV	2/48 (4.2)	na	na	na	na	2/48 (4.2)
Organ specific	0/23 (0.0)	na	na	na	na	0/23 (0.0)
HD	0/4 (0.0)	na	na	na	na	0/4 (0.0)

DM = dermatomyositis; dSSc = diffuse systemic sclerosis; HCV = hepatitis C virus; lSSc = limited systemic sclerosis; MCTD = mixed connective tissue disease; na = not analysed; HD = healthy donors; PM/Scl = polymyositis/scleroderma overlap syndrom; PM = polymyositis; RA = rheumatoid arthritis; SLE = systemic lupus erythematosus; UCTD = undifferentiated connective tissue disease

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

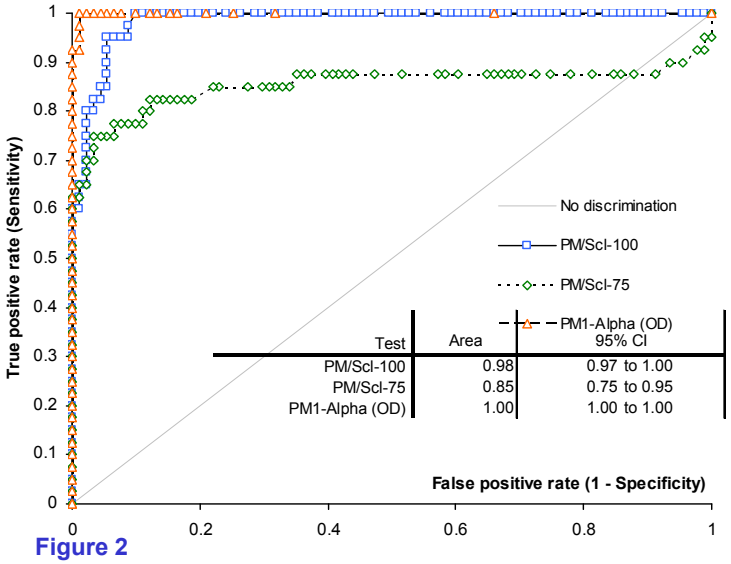

Figure 2

Receiver operating characteristics (ROC) analysis. 40 sera with anti-PM/Scl reactivity identified by indirect immunofluorescence on HEp-2 cells and confirmed by line immunoassay were tested in ELISA with recombinant PM/Scl-100, PM/Scl-75 and PM1-Alpha. Comparative ROC analysis shows good (PM/Scl-75) to excellent discrimination (PM1-Alpha) between predefined PM/Scl positive and negative samples (Mahler et al. 2009).

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, Raijmakers R, Dähnrich C, Blühtner M, Fritzler MJ. **Clinical evaluation of autoantibodies to a novel PM/Scl peptide antigen.** *Arthritis Research & Therapy* 2005, **7**:R704-R713 doi:10.1186/ar1729.
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6. Mahler M, Fritzler MJ. **PM1-Alpha ELISA: The assay of choice for the detection of anti-PM/Scl autoantibodies?** *Autoimmun Rev* 2009, **8**:373-378.

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