PM1-Alpha ELISA

The PM1-Alpha ELISA contributes to a better diagnosis of the PM/Scl Overlap Syndrome

Circulating antibodies to intracellular 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.

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.

PM1-Alpha ELISA Specifications

- Synthetic peptide 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

PM1-Alpha ELISA REF 25001 96

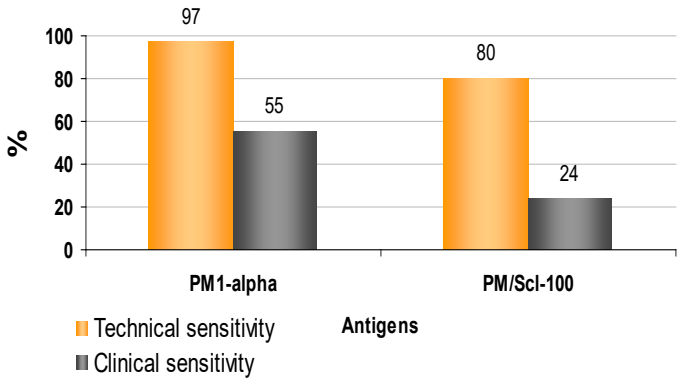

Figure 1
Technical and clinical sensitivity (in %) of PM1-Alpha peptide and recombinant PM/Scl-100. Anti-PM/Scl sera preselected based on Immunofluorescence and Immunoblot were tested for anti-PM/Scl antibodies using the PM1-Alpha peptide and the recombinant PM/Scl-100 protein. Moreover, samples from PM/Scl patients and various controls were assayed with the PM1-Alpha ELISA (REF: 25001). The clinical sensitivity for the recombinant protein was taken from the literature.

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

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Tabel 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

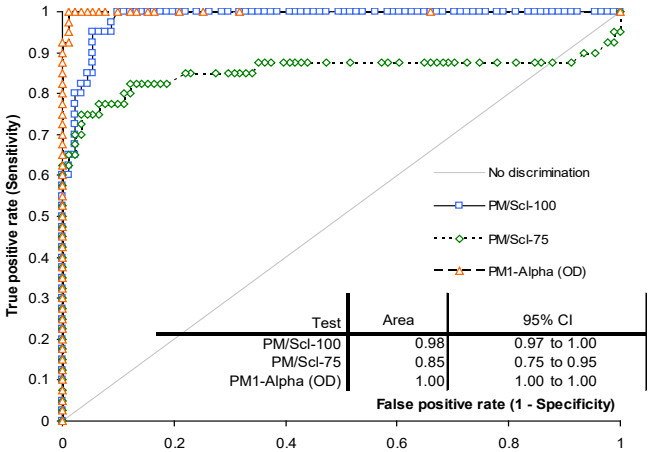

Figure 2
Receiver operating characteristics (ROC) analysis. 40 sera with anti-PM/Scl reactivity identified by indirect immunofluorescence on HEp-2 cells and confirmed by line immunoassay were tested in ELISA with recombinant PM/Scl-100, PM/Scl-75 and PM1-Alpha. Comparative ROC analysis shows good (PM/Scl-75)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

Literature

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