Anti-PM1-Alpha antibodies: Analytical evaluation in two centers

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Background: Anti-PM1-Alpha autoantibodies represent a serological marker for the systemic sclerosis and polymyositis overlap syndrome (PM/Scl). The objective was to analyse the analytical accuracy of anti-PM1-Alpha antibodies.

Methods: Sera were collected at the Rheumaklinik Aachen (center I) and Laboratoire Luxembourgeois d´immuno-Pathologie (center II). In center I samples were grouped into PM/Scl positive, negative and uncertain samples based on the consensus of indirect immunofluorescence (IIF) on HEp-2 cells and various confirmation tests (mainly immunodiffusion and line assay). Samples of center II were grouped into PM/Scl positive and negative samples based on IIF on HEp-2 cells and dot blot confirmation assay. All samples were tested by PM1-Alpha ELISA (Dr. Fooke Laboratorien). Samples from center II were also tested for anti-PM/Scl-75 and PM/Scl-100 reactivity by ELISA. Analysis for inter-batch variability of PM1-Alpha ELISA was done with two specimens.

Results and findings: In center I, 25/27 PM/Scl positive, 0/10 negative and 11/98 uncertain samples were PM1-Alpha positive.

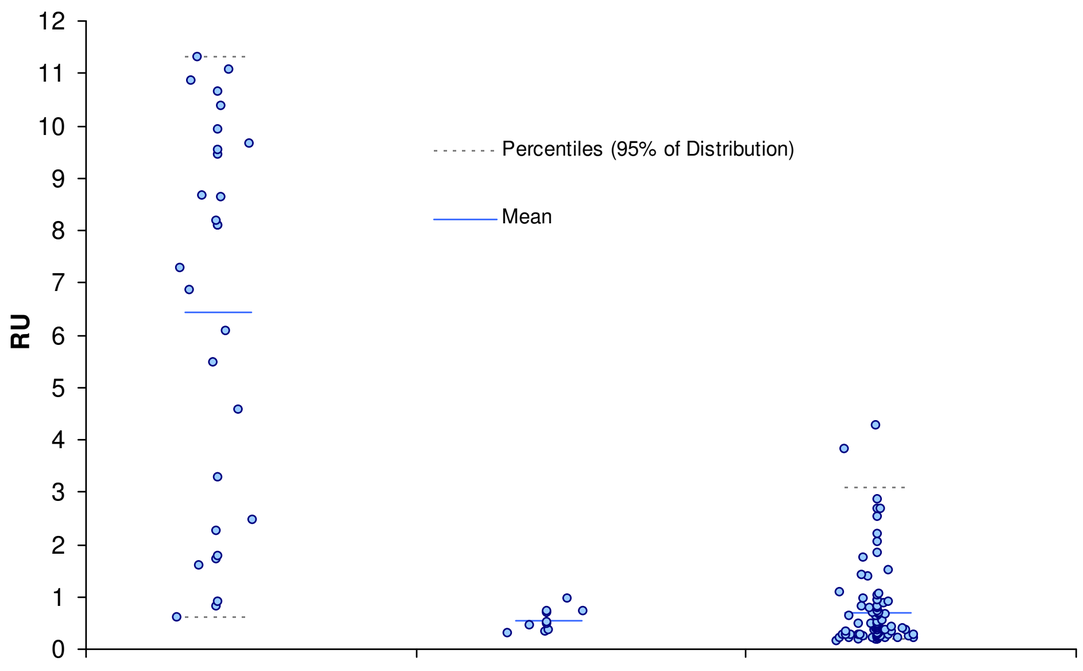

Figure 1 Comparative descriptive analysis in center I.

In center II, 39/40 anti-PM/Scl positive and 1/91 anti-PM/Scl negative samples (also PM/Scl-100 reactive) were anti-PM1-Alpha positive (one borderline). No clear quantitative correlation could be observed between the PM1-Alpha results with PM/Scl-75 (p=0.096), but with PM/Scl-100 (p=0.0021) and between PM/Scl-75 and PM/Scl-100 (p<0.0001). Comparative ROC analysis is shown in Figure 2. Inter-assay variability (CV%) was found between 2.5 and 8.8.

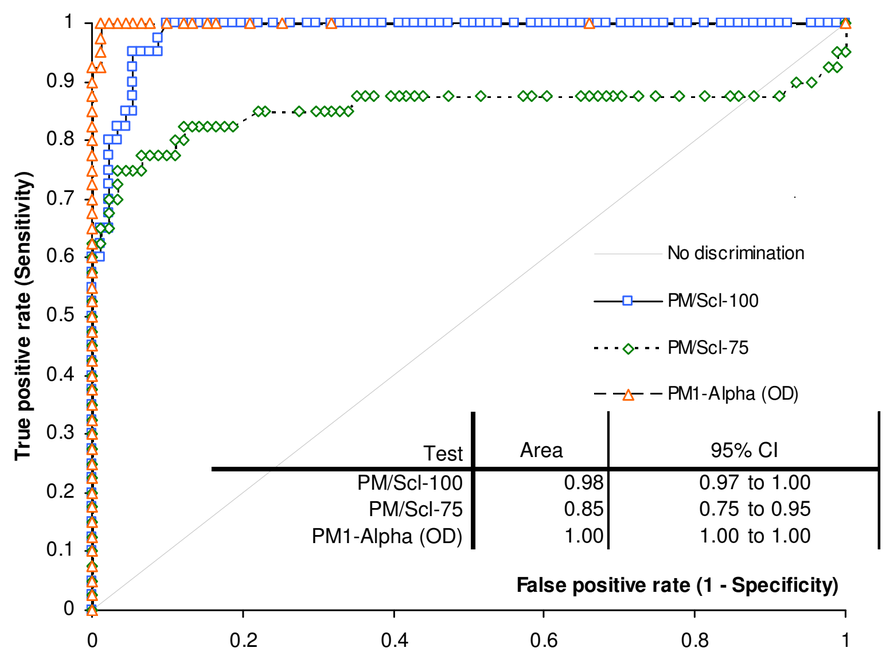

Figure 2 Receiver operating chararteristics (ROC) analysis in center II. Comparative ROC analysis shows good (PM/Scl-75) to excellent discrimination (PM1-Alpha) between predefined PM/Scl positive and negative samples.

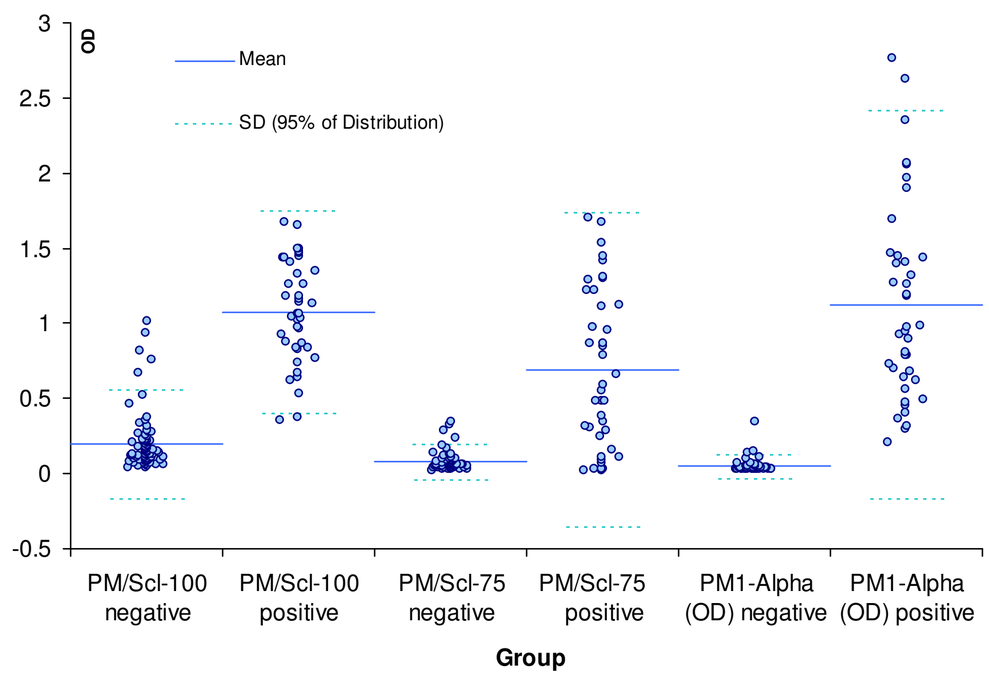

Figure 3 Comparative descriptive analysis in center II.

Table 1 Overview of the results obtained in two centers.

Cohort	No (%) > 1	No (%) > 1.5	Mean	Max
Defined PM/Scl positive				
PM/Scl Luxemburg (n=40)	40 (100%)	39 (97.5%)	6.2 RU	15.2 RU
PM/Scl Aachen (n=27)	25 (92.6%)	25 (92.6%)	6.6 RU	11.3 RU
PM/Scl all (n=67)	65 (97.0%)	64 (95.5%)	6.4 RU	15.2 RU
Defined PM/Scl negative / uncertain				
PM/Scl negative Luxemburg (n=91)	1/91 (1.1%)	1/91 (1.1%)	0.2 RU	1.6 RU
PM/Scl negative Aachen (n=10)	0 (0%)	0 (0%)	0.6 RU	1.0 RU
PM/Scl negative combined (n=101)	1/101 (1%)	1/101 (1%)	0.2 RU	1.6 RU
PM/Scl uncertain Aachen (n=98)	14 (14.3%)	8 (8.2%)	0.7 RU	4.3 RU

Conclusion: We conclude that the PM1-Alpha is superior to PM/Scl-75 or PM/Scl-100 based ELISAs for the detection of anti-PM/Scl antibodies.

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