

# EliA™ PM-Scl

## Safer differential diagnosis of connective tissue diseases

### Whom to test?

- Subjects in whom polymyositis/scleroderma (PM/SSc) overlap syndrome is suspected<sup>1</sup>.
- Subjects in whom scleroderma or childhood scleromyositis is suspected<sup>1</sup>.
- Subjects with unspecific symptoms, when differential diagnosis of myositis of unclear origin is the issue<sup>1</sup>.
- Patients showing symptoms of the myositis /scleroderma disease area, such as muscle weakness combined with elevated CK, lung fibrosis or Raynaud's phenomenon<sup>2</sup>.

### Why to test?

- Guidance in diagnostic decisions: PM-Scl antibodies are a specific marker for PM/SSc overlap syndrome<sup>3</sup>
- Useful for difficult differential diagnosis: PM-Scl antibodies occur in app. 24% of patients with PM/SSc overlap syndrome, but in only app. 3% of patients with scleroderma<sup>3</sup>.
- High clinical value of a positive result: App. 70% of PM-Scl-positive patients have PM/SSc overlap syndrome, app. 20% have idiopathic myositis and app. 10% have scleroderma<sup>1</sup>.
- Prognostic value: Cardiac and renal involvement is very rare in PM-Scl positive patients (1-3 %). Such patients have a relatively good prognosis<sup>1</sup>.

### When to test?

- If a positive result in indirect immunofluorescence on HEp-2 cells shows a nucleolar pattern – then in combination with other markers
- In case of a positive EliA CTD Screen result – then in combination with other markers

### Why EliA PM-Scl?

- First fully automated PM-Scl antibody test worldwide – saves time and money
- All EliA tests, from the EliA CTD Screen down to 16 single analyte ANA tests can be performed on the same instruments (Phadia 100, 250, 2500 and 5000) which are designed to fit every lab size.
- Delivers simple and fast results, independent of numbers of samples – best service to clinicians
- Almost no false positive results – high clinical usefulness



## Performance of EliA™ PM-Scl

Samples from 30 patients with PM/SSc overlap syndrome, 40 patients with polymyositis/dermatomyositis, 80 patients with scleroderma and 200 control patients with other diseases (connective tissue diseases, rheumatoid arthritis, infections, tumors) were investigated.

### ■ EliA PM-Scl is sensitive in detecting PM/SSc overlap syndrome

The test sensitivity of 20 % for PM/SSc overlap syndrome is in the range reported in the literature<sup>3</sup> (Fig 1.), and ~70% of positive patients have that disease entity or closely related entities<sup>1</sup>

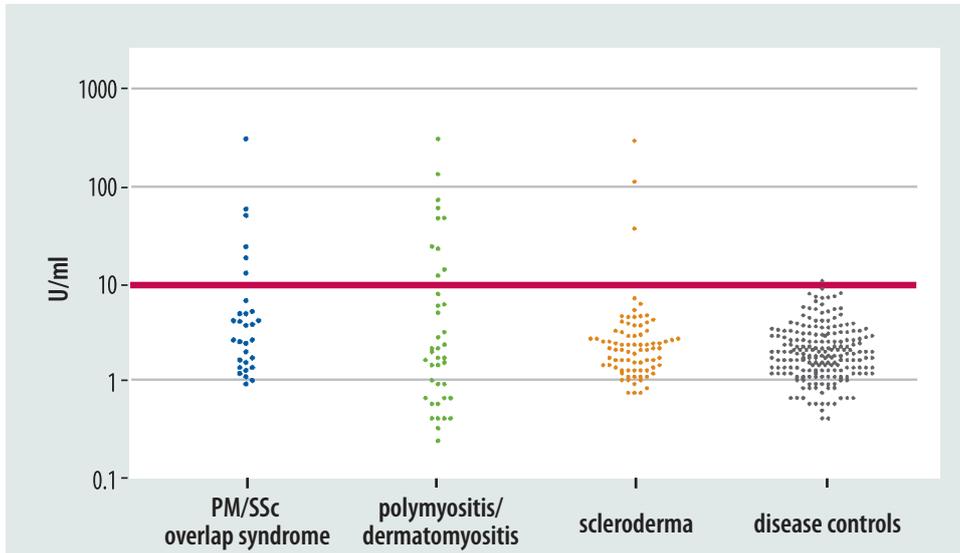


Figure 1: Clinical performance of EliA PM-Scl

### ■ EliA PM-Scl is very specific and gives results of high clinical value

The test specificity in diseased control patients is very high, assuring a high positive predictive value (PPV) and a high positive likelihood ratio (LR+) of the results (Table 1).

This gives positive test results a high clinical value in diagnostic decisions

Sensitivity	Specificity	PPV	LR+
PM/SSc overlap syndrome	Disease controls (n = 200)		For PM/SSc overlap syndrome
<b>20.0 %</b>	<b>99.5 %</b>	<b>95.0 %</b>	<b>40</b>

Table 1: Clinical performance of EliA PM-Scl. A LR+ of > 10 indicates high clinical relevance of the result.

## Ordering information

### Product

#### ■ EliA™ PM-Scl Well

### Article number

14-5602-01

### Content

24 determinations

For general reagents please see Phadia Autoimmunity Product Catalog.

## References

1. Conrad K et al (2002) In: Autoantigens, Autoantibodies, Autoimmunity, Vol 2 Conrad, Sack (eds), Pabst, Lengerich: pp 140-142
2. Hanke K et al (2009). Arth Res Ther 1: R22 (doi: 10.1186/ar2614)
3. Walker JG, Fritzler MJ (2007). Curr Opin Rheumatol 19: 580-591

# Phadia

Phadia GmbH, Munzinger Str. 7, D-79111 Freiburg, Germany, Tel: +49 761 47-805-0, Fax: +49 761 47-805-120, autoimmunity@phadia.com, www.phadia.com

Head office Sweden +46 18 16 50 00 Austria +43 1 270 20 20 Belgium +32 2 749 55 15 Brazil +55 11 3345 5050 Czech Republic +46 18 16 63 65 Denmark +45 70 23 33 06 Finland +358 9 8520 2560 France +33 1 6137 3430 Germany +49 761 47 805 0 Italy +39 02 64 163 411 Japan +81 3 5365 8332 Norway +47 21 67 32 80 Portugal +351 21 423 53 50 Spain +34 935 765 800 South Africa +27 11 792 6790 Switzerland +41 43 343 40 50 Taiwan +886 2 2516 0925 The Netherlands +31 30 602 37 00 United Kingdom / Ireland +44 1908 847 034 Other Countries +46 18 16 50 00