

# An integral part of your diagnostic screening algorithm for CTDs



EliA™ Symphony<sup>s</sup> – designed for high clinical accuracy  
Fully automated and perfectly aligned CTD differentiation

# Addressing the challenges of CTDs

## EliA Symphony<sup>s</sup> helps differentiate between CTD and non-CTD patients

CTDs (connective tissue diseases) are a group of closely related multisystem conditions with many similar clinical features.<sup>1</sup> The diverse and overlapping symptoms, particularly early in the course of the disease, make diagnosis challenging.<sup>2</sup> Prompt referral to specialist care is essential to prevent avoidable organ damage or other severe clinical consequences.<sup>1</sup> The determination of disease-specific antibodies, e.g., ENAs (Extractable Nuclear Antigens), is of central importance for clinical diagnosis.<sup>1-4</sup>

	▶ Most common ————— ▶ least common CTD				
	Sjögren's	SLE	Scleroderma	PM/DM	MCTD
SS-A/Ro	70–100% <sup>5</sup>	40–50% <sup>6,7</sup>	15–20% <sup>8</sup>	–	–
SS-B/La	40–90% <sup>5</sup>	6–15% <sup>6,9</sup>	–	–	–
U1RNP (A,C,70)	–	30–40% <sup>6,10</sup>	2–14% <sup>8</sup>	–	> 95% <sup>6,10</sup>
SmD	–	20–30% <sup>6,10</sup>	–	–	–
Centromere B	–	–	70–90% limited <sup>6</sup>	–	–
Scl-70	–	–	up to 70% diffuse <sup>6</sup>	–	–
Jo-1	–	–	–	~ 25% <sup>6</sup>	–

**Table 1: Prevalence of autoantibodies most commonly found in different CTDs.** Sjögren's syndrome, systemic lupus erythematosus (SLE), polymyositis/dermatomyositis (PM/DM), mixed connective tissue disease (MCTD).

### ▶ Testing for relevant autoantibodies in conjunction with a thorough clinical history can help diagnose CTDs earlier<sup>1,3,4</sup>

#### EliA Symphony<sup>s</sup> – optimal presentation of the most important markers\*

For maximum clinical value EliA Symphony<sup>s</sup> comprises **human recombinant U1RNP (RNP70, A, C), SS-A/Ro (60 kDa, 52 kDa), SS-B/La, Centromere B, Scl-70, Jo-1 proteins and synthetic SmD<sub>3</sub> peptide.**

The antigens are bound to the EliA Well with an updated coating method. This results in better antigen presentation, better accessibility of epitopes and therefore higher sensitivity compared to EliA Symphony (see table 2).

Using recombinant antigens minimizes contamination, avoids harsh, protein-altering purification processes and ensures a high lot-to-lot consistency within and between lots.<sup>11</sup>

EliA Symphony<sup>s</sup> uses IgG Calibrators, which are traceable via an unbroken chain of calibrations to the WHO International Reference Preparation (IRP) 67/86.<sup>3</sup>

### ▶ A clinically relevant first-line screen which complies to CTD classification criteria<sup>12-16</sup>

\* EliA dsDNA is available as a separate assay.

# An integral diagnostic approach

## Perfect alignment of EliA Symphony<sup>s</sup> and *all* single EliA CTD differentiation tests

### EliA SmD<sup>p</sup> and EliA Scl-70<sup>s</sup> are now synchronized with EliA Symphony<sup>s</sup>

EliA SmD<sup>p</sup> is coated with synthetic SmD<sub>3</sub> peptide, a scientifically advanced approach compared to conventionally purified Sm leading to improved clinical performance.<sup>17</sup>

EliA Scl-70<sup>s</sup> uses the same recombinant antigen as EliA Scl-70, but the test is more sensitive due to an updated coating method allowing improved epitope presentation.<sup>18</sup>

### ► Benefit from a seamless testing cascade with aligned high quality tests at every step

### EliA Symphony<sup>s</sup> – designed for optimal clinical performance

Selection of the most clinically relevant antigens in conjunction with an enhanced assay design leads to a great balance of sensitivity and specificity.

	EliA Symphony <sup>s</sup>	EliA Symphony
Sensitivity	66.6 %	66.1 %
Specificity	93.0 %	92.1 %
LR +	9.53	8.41
LR -	0.36	0.37

Table 2: Internal study based on 633 clinically defined serum samples: 404 CTD patients, 229 disease controls (data on file).<sup>19</sup>

### ► Improved combination of sensitivity and specificity leads to high clinical accuracy

The resulting high **positive likelihood ratio** gives greater confidence in the diagnostic decision, and helps to

- Identify true CTD patients
- Miss fewer CTD patients
- Minimize anxiety and diagnostic delay
- Reduce workload and unnecessary testing
- Prevent patients receiving incorrect therapies

## EliA Symphony<sup>s</sup> – simplified autoimmunity diagnostics on an intuitive, automated, tailor-made platform



Increase of operational efficiency and quality of service with the right instrument solution (Phadia 100, Phadia 250, Phadia 2500/5000).

- ▶ Fully automated **detection of antibodies associated with CTDs** combined with renowned EliA quality
- ▶ **Easy integration** into laboratory workflow through full automation and reflex testing possibility minimizing workload for lab staff
- ▶ Designed for optimal presentation of the most important markers for CTDs\*
- ▶ **Perfect alignment** of EliA Symphony<sup>s</sup> and single EliA CTD differentiation tests
- ▶ **High clinical accuracy** through further improved combination of sensitivity and specificity

\* EliA dsDNA is available as a separate assay.

## ▶ Fully automated testing with EliA Symphony<sup>s</sup> – an extension of the excellent EliA Symphony track record

### References

1 Ahmad Y, et al. *Collected reports on the rheumatic diseases* 2005;4:85-88 2 Gaubitz M. *Rheumatology* 2006;45:iii3-iii4 3 EliA Symphony<sup>s</sup> Directions for Use 4 EliA Jo-1 Directions for Use 5 Yoshimi R, et al. *Clin Dev Immunol.* 2012; Article ID: 606195 6 Tan EM, *Immunologist* 1999;7:85-92 7 Reichlin M, Scofield H, in : Peter JB, Shoenfeld Y (eds), *Autoantibodies* 1996;783-788, Elsevier, Amsterdam 8 Mehra S, et al. *Autoimmun Rev.* 2013;12:340-354 9 Keech CL, McCluskey J, Gordon TP, in: Peter JB, Shoenfeld Y (eds), *Autoantibodies* 1996;789-797, Elsevier, Amsterdam 10 Peng SL, Craft JE, in: Peter JB, Shoenfeld Y (eds), *Autoantibodies* 1996;774-782, Elsevier, Amsterdam 11 Schmitt J, Papisch W, *Autoimmun Rev.* 2002;1:79-88 12 Hochberg MC, *Arthritis Rheum* 1997;40:1725 13 Petri M, et al. *Arthritis Rheum* 2012;64:2677-2686 14 Alarcon-Segovia D, Villarreal M, in: Kasukawa R, Sharp GC (eds) *Mixed Connective Tissue Disease and Antinuclear Antibodies*, 1987;33-40, Elsevier, Amsterdam 15 Van den Hoogen F, et al. *Arthritis Rheum* 2013;65:2737-2747 16 Tanimoto K, et al. *J Rheumatol* 1995;22:4 17 Mahler M, et al. *Clinical and Diagnostic Laboratory Immunology* 2005;12:107-113 18 Internal study (data on file)

### Technical data

Ordering information	Article No.	Package size	Cut-off			Short name
			negative	equivocal	positive	
EliA Symphony <sup>s</sup>	14-5671-01	4 x 16 wells	< 0.7 ratio	0.7–1.0 ratio	> 1.0 ratio	sys