

The Diagnostic Performance of the Novel EliA SymphonyS anti-ENA Screen

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Introduction: TFS/Phadia recently developed a novel version of the EliA Symphony, the Symphony Sensitive (S), for improved screening antibodies to extractable nuclear antigens (ENA, including SS-A/Ro, SS-B/La, U1RNP, Sm, Scl-70, Centromere B and Jo-1) in patients suspected for systemic autoimmune rheumatic disease (SARD). Compared to the EliA Symphony the Scl-70 substrate has been biotinylated and is bound to solid phase streptavidin, and the purified Sm substrate has been replaced by synthetic SmD3 peptide.

Methods: ENA antibody analysis by fluorescence enzyme immunoassay (FEIA), using the Phadia250 random access system (Thermo Fisher Scientific)

Analyzed serum samples:

- unselected prospective study population of 247 patients, suspected of SARD and submitted for routine ANA (IIF on HEp2) testing
- retrospective population of 150 patients previously diagnosed with SARD, including SLE (n=50), SjS (n=40), SSc (n=30) and PM/DM (n=30)
- apparently healthy blood donors (n=100)

Diagnostic performance: Sensitivity and specificity were calculated for the prospectively included cohort based on diagnosis SARD (SLE, SjS, SSc, PM/DM, MCTD) versus non-SARD, and for the retrospectively included SARD cohort in combination with results obtained with healthy blood donors



Pros-/retro-
spective
study

EliA™

Results 1: EliA SymphonyS compared to EliA Symphony in a cohort of prospectively included patients suspected of SARD

ANA positive patients	total	Symphony neg	Symphony pos	SymphonyS neg	SymphonyS pos
SARD (n)	61	10	51	8	53
non-SARD (n)	60	51	9	51	9
sensitivity (%)		83,6		86,9	
specificity (%)		85,0		85,0	
ANA negative patients	total	Symphony neg	Symphony pos	SymphonyS neg	SymphonyS pos
SARD (n)	7	5	2	5	2
non-SARD (n)	119	114	5	104	15
sensitivity (%)		28,6		28,6	
specificity (%)		95,8		87,4	

Results 2: EliA SymphonyS compared to EliA Symphony in a cohort of retrospectively included SARD patients and healthy controls

patients and controls	total	Symphony neg	Symphony pos	SymphonyS neg	SymphonyS pos
SLE (n)	50	13	37	13	37
SjS (n)	40	12	28	11	29
SSc (n)	30	12	18	12	18
PM/DM (n)	30	21	9	21	9
SARD (n)	150	58	92	57	93
controls (n)	100	97	3	97	3
sensitivity (%)		61,3		62,0	
specificity (%)		97,0		97,0	

Conclusion: Our study indicates increased diagnostic sensitivity of the novel EliA SymphonyS anti-ENA antibody screening test when compared to the original EliA Symphony. When EliA SymphonyS is employed only for ANA IIF positive patients suspected of SARD, diagnostic specificity is not affected.