Autoimmunity

LIAISON® ENA Screen

Extractable Nuclear Antigens (ENA)

Extractable Nuclear Antigens (ENA) assay detects a group of autoantibodies that attacks substances found in the nucleus of all type of cells. These autoantibodies are found in an extraordinarily high frequency of systemic rheumatic diseases. Although these antibodies were first associated with Systemic Lupus Erythematosus (SLE), a series of rheumatic diseases have now been shown to be characterized by the presence of one or more of these ENAs. For instance, SS-A (Ro) and SS-B (La) are associated with SLE and Sjogren's Syndrome (SS), anti-Sm antibodies with SLE and anti-RNP antibodies with SLE and Mixed Connective Tissue Disease (MCTD). In addition, scleroderma (Progressive Systemic Sclerosis, PSS) is characterized by the presence of anti-Scl-70 antibodies, polymyositis and dermato-myositis by the presence of anti-Jo-1 antibodies, while CREST syndrome by the presence of anti-centromere antibodies. The determination of antinuclear antibodies is nowadays considered of paramount importance for the clinical diagnosis of connective tissue diseases.

LIAISON® ENA Screen assay

DiaSorin introduces LIAISON® ENA Screen, an assay suitable for innovative automation in the field of autoimmunity. LIAISON® ENA Screen is intended for screening of the presence of ENA antibodies in patients with suspected Connective Tissue Disease (CTD) or to be used as a reflex test of ANA Screen assay. Advantages over current testing technologies are expected in terms of higher specificity and sensitivity for the diagnostically relevant ENA specificities and quicker process to obtain results.

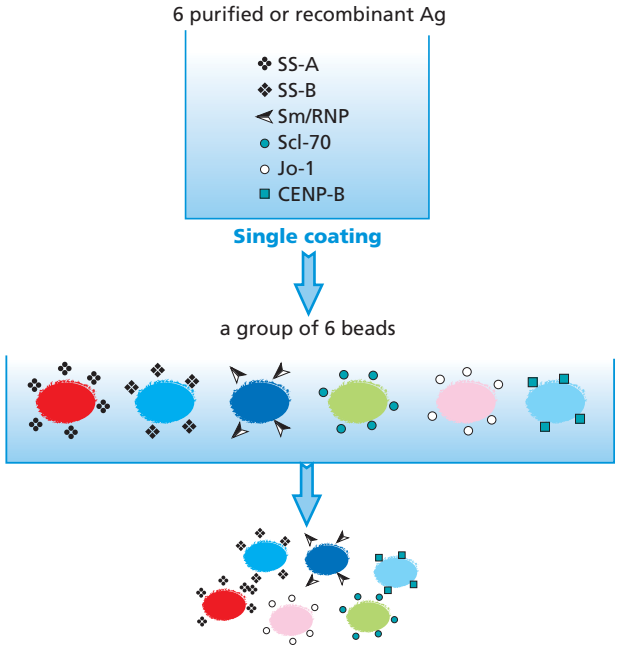
Antigen coating

The coating uses highly purified or recombinant clinically relevant antigens.

- **Recombinant antigens:** Jo-1, Scl-70, CENP-B, SS-B (La)
- **Native purified antigens:** Sm/RNP, SS-A (Ro)

Each antigen is separately coated on paramagnetic microparticles, in optimized conditions. Coated particles are separately checked for performance and then pooled to obtain the optimal mixture for the collective determination of ANA specificities (**Fig. 1**).

Fig. 1



Production and Quality Control (QC) of single antigens coated beads are performed individually.
Only QC approved individual coated beads are pooled and used
for the production of the **Integral reagent**

LIAISON®

Clinical performance

499 specimens were tested using LIAISON® ENA Screen and a reference ELISA test (**Table 1**).

After further analysis of discrepant results with a dot blot method, three specimens remained unresolved and therefore were not included in the data analysis.

Diagnostic sensitivity (including eqv as reactive): 97.4% (95% confidence interval: 86.5 - 99.9%)

Diagnostic specificity: 98.91% (95% confidence interval: 97.47 - 99.64%)

A second population of 131 specimens was tested (**Table 2**). The presence of specific ENA antibodies is reported in the following table, as detected by reference methods (ELISA and dot blot methods), as well as by LIAISON® ENA Screen assay.

Table 1

Reference ELISA method after resolution of discrepancies

LIAISON® ENA Screen	neg	eqv	pos	
neg	452	1	1	454
eqv	1	1	1	3
pos	4	1	37	42
	457	3	39	499

Table 2

Presence of ENA antibodies as detected by reference methods	No. of samples (%)		Interpretation neg. (%)		equiv. (%)		pos. (%)	
anti-SS-A (Ro), anti-SS-B (La)	82	(62.6%)	2/82	(2.4%)	1/82	(1.2%)	79/82	(96.3%)
anti-RNP/Sm	14	(10.7%)	1/14	(7.1%)	0/14	(0.0%)	13/14	(92.9%)
anti-Scl-70	17	(13.0%)	1/17	(5.9%)	0/17	(0.0%)	16/17	(94,1%)
anti-Jo-1	7	(5.3%)	0/7	(0.0%)	0/7	(0.0%)	7/7	(100%)
anti-Centromere (CENP-B)	11	(8.4%)	1/11	(9.1%)	0/11	(0.0%)	10/11	(90.9%)
Total	**131**	**(100%)**	**5/131**	**(3.8%)**	**1/131**	**(0.8%)**	**125/131**	**(95.4%)**

LIAISON® ENA Screen maximises the efficiency of your routine

Ease of use and quick results

- **Full automation** makes daily routine convenient and easy
- **Barcoded samples** and **reagents**
- **Calibration** stable for 2 weeks
- **Flexible assay protocols**
- **Continuous reagent inventory**
- **Calibrators** included
- **High throughput:** 86 results/hour
- **Time to first result:** 35 min
- **Stored master curve**
- **Small sample volume:** 20 µL