

LIAISON® ANA Screen

■ Anti Nuclear Antibodies

The presence of anti nuclear antibodies (ANA) occurs with high frequency in systemic autoimmune diseases such as Systemic Lupus Erythematosus (SLE), Sjögren's Syndrome (SS), Mixed Connective Tissue Disease (MCTD), scleroderma, CREST syndrome, Polymyositis (PM), etc. The most traditional analytical method used to test ANAs is Indirect Immunofluorescence Assay (IFA), using the HEp-2 cells as substrate. However, substrate variations, manual performance, subjective interpretation and microscope variability result in low reproducibility and lack of standardization. A relevant number of patients with non-autoimmune diseases and even apparently healthy individuals may be IFA ANA HEp-2 positive.

■ LIAISON® ANA Screen assay

DiaSorin introduces LIAISON® ANA Screen for screening the presence of ANAs in serum of patients with suspected Connective Tissue Disease (CTD).

LIAISON® ANA Screen changes the rules of the diagnostic algorithm for CTD, being designed to maximize the

Positive Predictive Value (PPV) and therefore the efficiency of the routine practice, without compromising its sensitivity towards samples having specific and clinically relevant ANAs.

■ Antigen coating

LIAISON® ANA Screen uses single paramagnetic beads coated in optimized conditions via covalent coupling with highly purified and recombinant clinical relevant autoantigens: purified SS-A (Ro) and RNP/Sm, recombinant SS-B (La), Scl-70, Jo-1, CENP-B, mitochondria and synthetic dsDNA and HEp-2 nuclear extracts.

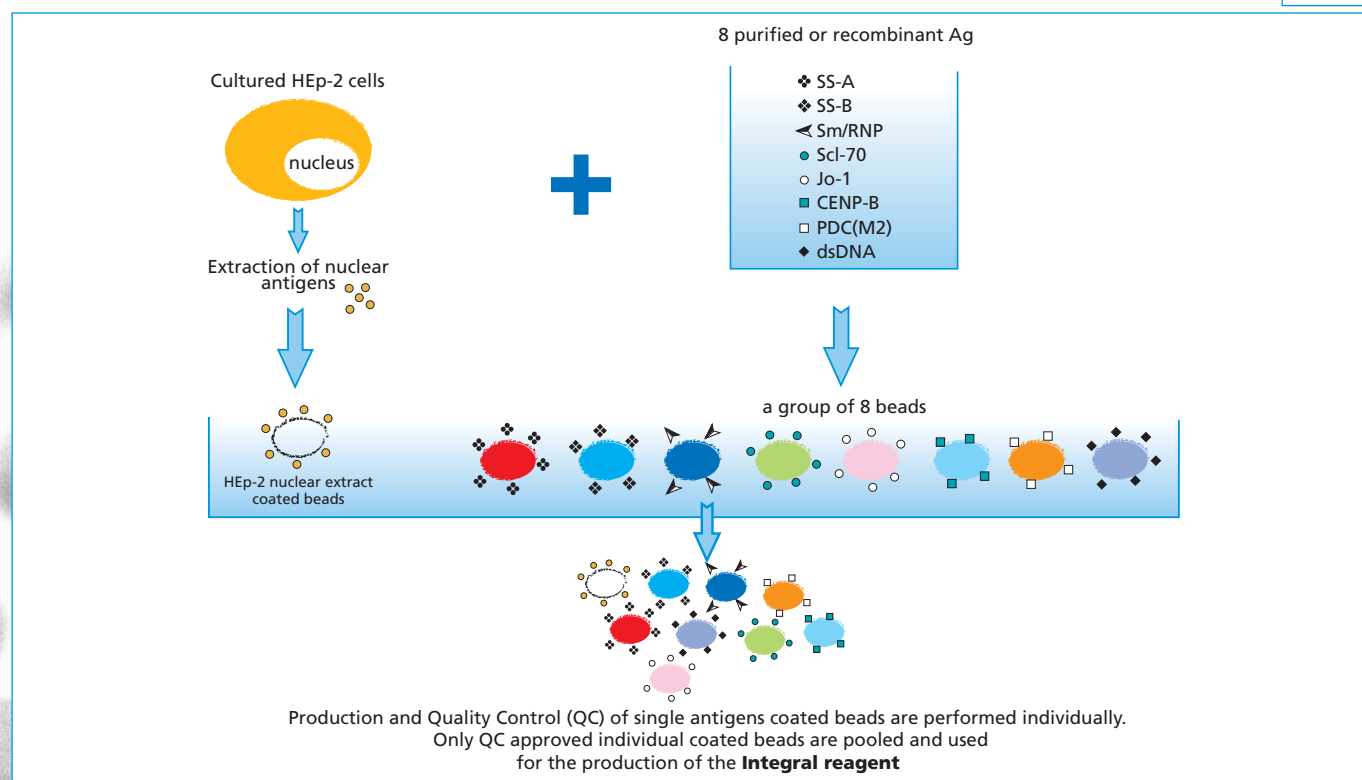
■ Excellent Sensitivity

High quality antigens and large coated surface allow LIAISON® ANA Screen to offer the best sensitivity for the detection of the most clinically relevant autoantibodies.

■ Excellent reproducibility

Coated particles are separately controlled for performance and then blended to obtain the optimal mixture for high reproducibility and standardized determination of ANA specificities (**Fig. 1**).

Fig. 1



Clinical performance

529 samples were tested with the LIAISON® ANA Screen assay: 87 samples (16.4%) out of 529 were previously classified as IFA positive, and 442 (83.6%) out of 529 were previously classified as IFA negative (**Table 1**).

LIAISON® ANA Screen displays dramatically improved PPV

with respect to IFA. Samples showing non-specific fluorescence patterns will score negative as well as samples with low levels of antibodies, that can be present in non autoimmune patients and healthy individuals.

A second population of 134 specimens was tested, obtained from patients affected by clinically defined connective tissue diseases (**Table 2**).

Table 1

	LIAISON® ANA Screen
Diagnostic specificity	97.6%
Diagnostic sensitivity	96.3%
PPV	83.9%
NPV	99.5%

PPV (Positive Predictive Value): probability that a person with a positive result has the disease

NPV (Negative Predictive Value): probability that a person with a negative result does not have the disease

Table 2

Disease	No./total	% positive by LIAISON®	Expected % positive by IFA *
Systemic lupus erythematosus	65/74	87.8	95-100
Sjögren's syndrome	25/26	96.1	40-70
Polymyositis	2/2	100	30-80
CREST syndrome	4/4	100	20-60
Mixed connective tissue disease	6/6	100	100
Systemic sclerosis	18/22	81.8	60-80

* Kavanaugh et al. Arch Patol Lab Med 2000;124:71

LIAISON® ANA Screen maximise 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