ANA Screen ELISA

REF 25012

Background

Circulating antibodies to intra-cellular structures especially to nuclear antigens represent a characteristic feature of systemic autoimmune diseases. Among the most important ones are double-stranded DNA (dsDNA), Ro52, Ro60, La, centromere proteins, Scl-70 (topoisomerase I, topo I), RNP/Sm, Sm, Jo-1 and PM/Scl. Many of those antigens are considered as specific marker for a certain autoimmune disease whereas others show moderate specificity (see table 1). Since in the indirect immunofluorescence (IIF) test a few clinically relevant antibodies (e.g. Ro60 (SS-A), Ro52, Jo-1) are hardly detectable, the ANA Screen ELISA represents a useful alternative method to IIF.

Table 1 Overview of the autoantigens

Antigen	Disease association
dsDNA (r)	Systemic lupus erythematosus (SLE)
Ro52 (r)	SjS, PM, SLE, SSc
Ro60 (r)	Sjögren Syndrome (SjS)
La (r)	Sjögren Syndrome (SjS)
RNP/Sm (n)	Mixed connective tissue disease
Sm (n)	SLE
Jo-1 (r)	Polymyositis (PM)
Scl-70 (r)	Systemic sclerosis (SSc)
CENP (r)	Systemic sclerosis (SSc)
PM1-Alpha (s)	PM/SSc overlap syndrome

r = recombinant, n = native, s = synthetic

Intended use

The ANA Screen ELISA is intended for the semi-quantitative determination of antinuclear antibodies (ANAs). The results of the ANA Screen ELISA aid to the diagnosis of systemic autoimmune diseases. The test should be used as initial screening test.

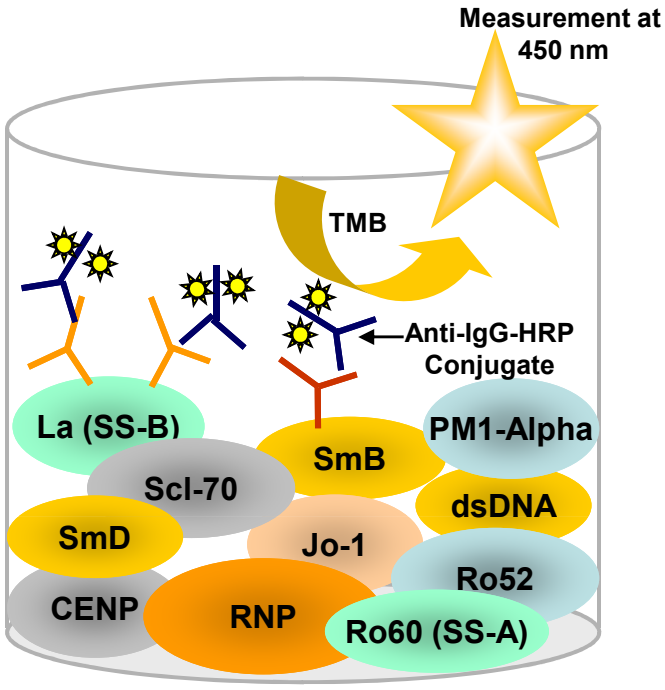

Figure 1 Test principle ANA Screen ELISA
The wells of the ANA Screen ELISA are coated with a mixture of native, recombinant and synthetic autoantigens (see Table 1). During the first step diluted patient sample is incubate in the wells. During the incubation time, the autoantibodies contained in the sample will bind to coated antigens. After washing steps and conjugate- and substrate–incubation these complexes can be quantified by photometric analysis.

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General features

- CE marked
- User-friendly
- Colored reagents
- Ready to use reagents (except washing buffer)
- Breakapart mircotiter strips

Technical information

- Assay time: < 1.5 h at RT (30 min /30 min /15 min)
- 3 µL serum or plasma per test
- Detection System: HRP/TMB ($OD_{450\ nm\ /\ 620\ nm}$)
- Wide measuring range
- Low detection limit

ID	Target	ELISA (RU)	Interpretation
CDC 1	DNA	3.8	positive
CDC 2	SS-B/La	2.6	positive
CDC 3	RNP/Sm, SS-A/Ro, SS-B/La	5.0	positive
CDC 4	U-1 RNP	5.2	positive
CDC 5	Sm	4.4	positive
CDC 6	Fibrillarin	1.0	borderline
CDC 7	SS-A/Ro	1.9	positive
CDC 8	Centromere	2.6	positive
CDC 9	Scl-70	2.6	positive
CDC 10	Jo-1	4.6	positive
CDC 11	PM/Scl (PM 1)	1.3	borderline
CDC 12	Rib-P	0.7	negative

Figure 2
Results of the CDC ANA reference sera. 12 reference serum samples, available from the "Center for Disease Control and Prevention (CDC)" were tested in the ANA Screen ELISA (REF: 25012). All sera, except CDC 6, 11 and 12 have been tested positive. CDC 6 and 11 are borderline and CDC 12 is negative. The borderline result of CDC 6 and the negative result of CDC 12 can be explained by the absence of Fibrillarin and Rib-P in the ANA Screen.

Assay performance

- Good correlation to reference ELISA systems
- Excellent "lot to lot" correlation $R^2 > 0.9$
- Low intra- and inter-assay variation
- The clinical specificity against apparently healthy blood donors has been determined as 100% in a cohort of Caucasian SLE patients
- The clinical sensitivity for SLE in a Caucasian SLE cohort has been found at 85% (cut-off 1.0 RU)

Table 2 Precision (intra-assay variation) of the ANA Screen ELISA

Serum	Mean RU	CV %
ANA/1 (n=4)	3.1	2.2
ANA/2 (n=4)	3.5	7.1
ANA/3 (n=4)	4.0	6.0

Table 3 Precision (inter-assay variation) of the ANA Screen ELISA

Serum	Mean RU	CV %
ANA/1 (n=8)	2.5	11.1
ANA/2 (n=8)	3.6	3.2
ANA/3 (n=8)	3.9	9.1

Literature

1. Tan EM: **Antinuclear antibodies: diagnostic markers for autoimmune diseases and probes for cell biology**. *Adv Immunol 1989*, **44**:93-151.
2. Hoffman IE, Peene I, Veys EM, De Keyser F: **Detection of specific antinuclear reactivities in patients with negative anti-nuclear antibody immunofluorescence screening tests**. *Clin Chem 2002*, **48**:2171-2176.
3. Mahler M, Raijmakers R, Fritzler MJ: **Challenges and Controversies in Autoantibodies Associated with Systemic Rheumatic Diseases**. *Curr Rheumatol Rev* 2007, **12**:67-78.
4. Mahler M, Eisfeller P, Silvermann ED, Fritzler MJ: **Diagnostic value of a novel ANA Screen ELISA.** *10th International Workshop on autoantibodies and autoimmunity, Guadalajara* 2008.

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