ENA Profile 8 ELISA

The ENA Profile 8 ELISA contributes to the diagnosis of systemic autoimmune diseases

Circulating IgG autoantibodies (aab) to intracellular structures especially to extractable nuclear antigens (ENA) represent a characteristic feature of systemic autoimmune diseases. Among the most important ones are double-stranded DNA (dsDNA), Ro, La, centromere proteins, Scl-70 (topoisomerase I, topo I), the Smith antigen (Sm), Ribonucleoproteins (RNP), Jo-1 and PM/Scl. Aab against dsDNA and the Sm Complex rate as highly-specific markers for the systemic lupus erythematosus (SLE) and can be detected in 5-30% (Sm) and 20-70% (dsDNA) of SLE patients. Based on the high disease-specificity of anti-Sm and anti-dsDNA aab they were included as diagnose criteria of the American College of Rheumatology (ACR).

Anti-RNP aab are considered as SLE associated antibodies which are also found in other inflammatory autoimmune disorders. Systemic sclerosis (SSc) is characterized by the occurrence of anti-Scl-70 and anti-CENP aab. Aab to Ro52 and La (SS-B) can be detected in samples from SLE, sjögren syndrome (SjS), mixed connective tissue disease (MCTD) and SSc patients. Anti-Jo-1 aab were first described in the serum of a myositis patient.

The ENA Profile 8 ELISA is intended for the semi-quantitative determination of ENAs and adds to the diagnosis of systemic, rheumatic autoimmune disorders.

ENA Profile 8 Screen ELISA Specifications

- Colored reagents
- Assay time < 1,5 h at RT (30min /30min/ 15min)
- 3 µL serum or plasma per test
- Detection System: HRP/TMB ($OD_{450nm\ /620\ nm}$)
- Wide measuring range
- Low detection limit

ENA Profile 8 ELISA REF 25023 8x12

Table 1 Overview of the autoantigens

Line	Antigen	Disease association	Prevalence
A	dsDNA	SLE	20-70%
B	RNP/Sm	SLE, MCTD, SSc	5-30%
C	Sm	SLE	5-20%
D	Ro52	SLE, SjS, SSc	20-90%
E	La (SS-B)	SLE, SjS	10-30%
F	Scl-70	SSc	20-40%
G	CENP-B	SSc	10-20%
H	Jo-1	Myositis	20-40%

Figure 1
The ENA Profile 8 ELISA contains microtiterstrips (8x12 wells) coated with 8 different autoantigens.

Assay performance

- Good correlation to reference ELISA systems
- Excellent "lot to lot" correlation $R^2 > 0.9$
- Low intra- and inter-assay variation
- Excellent linearity

(r=recombinant;n=native;s=synthetic)

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ID	Target	Positive results in the ENA Profile 8 ELISA to the following antigens
CDC 1	DNA, Sm	dsDNA RNP/Sm Sm
CDC 2	SS-B/La	La Ro52
CDC 3	RNP/Sm, SS-A/Ro, SS-B/La	La Ro52 RNP/Sm Sm
CDC 4	U-1 RNP	RNP/Sm
CDC 5	Sm	RNP/Sm Sm
CDC 6	Fibrillarin	-
CDC 7	SS-A/Ro	Ro52
CDC 8	Centromere	CenpB
CDC 9	Scl-70	Scl-70
CDC 10	Jo-1	Ro52 Jo-1
CDC 11	PM/Scl (PM 1)	-
CDC 12	Rib-P	-

Table 2
Results of the CDC ANA reference sera. 12 reference serum samples, available from the "Center for Disease Control and Prevention (CDC)" were tested to all 8 antigens containing in the ENA Profile 8 ELISA. All sera, except CDC 6, 11 and 12 have been tested positive. The negative results of CDC 6, 11 and 12 can be explained by the absence of PM1-Alpha, Fibrillarin and Ribosomal-P in the ENA Profile 8 ELISA.

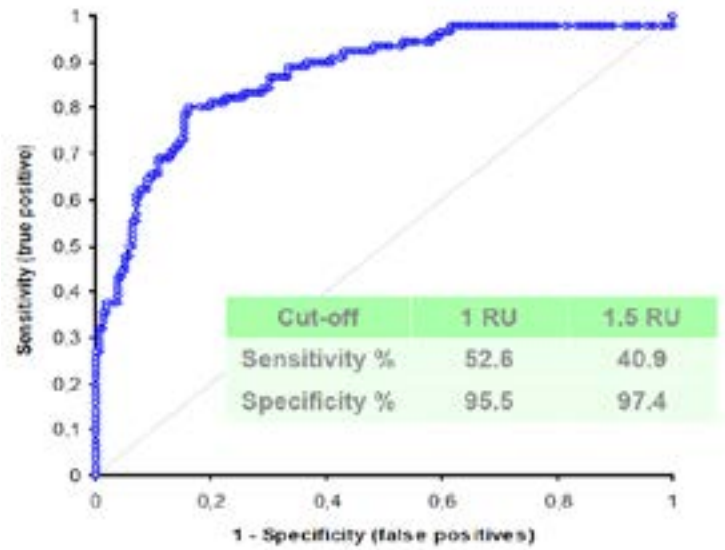

Figure 2
Receiver operating characteristics (ROC) analysis. 171 serum samples from patients with SLE and 156 controls were tested for anti-dsDNA antibodies. The results show a good differentiation between SLE patients and controls as revealed by an area under the curve value (AUC) of 0.87. The sensitivity and specificity of the test in this patient group was determined as 40.9 % and 97.4 %, respectively.

Literature

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