Ribosomal P ELISA

REF 25002

Background

Circulating autoantibodies (aab) to intra-cellular structures especially to nuclear antigens represent a characteristic feature of systemic autoimmune diseases. Anti-ribosomal P (Rib-P) aab can be found in 10-40% of SLE patients with a high degree of disease specificity. The prevalence has been reported to be dependent on a number of factors such as the assay system, the genetic background of the patients and most important, the patient selection. Anti-Rib-P aab are mainly directed against the C-terminal region of the human ribosomal P proteins which is shared among the three polypeptides P0 (38 kDa), P1 (19 kDa) and P2 (17 kDa). A synthetic peptide comprising the C-terminus of the ribosomal P proteins has been identified and characterized as a highly sensitive and specific antigen for the detection of anti-Rib-P aab. A recent investigation has shown limited sensitivity of the indirect immunofluorescence technique for the detection of anti-Rib-P aab and significant variations among different slide manufacturers.

Intended use

The Ribosomal P ELISA is intended for the semi-quantitative determination of a subpopulation of anti-Rib-P antibodies and thus contributes to the diagnosis of SLE. Since patients with anti-Rib-P antibodies frequently suffer from neurological disturbances and severe disease progression, anti-Rib-P antibodies are considered as important biomarker for the prognosis of SLE patients. Furthermore, anti-Rib-P aab should be tested in case of suspected SLE using the ELISA.

General features

- Synthetic peptide antigen
- CE marked
- User-friendly
- Colored reagents
- Ready to use reagents (except washing buffer)
- Breakapart microtiter 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	0.4	negative
CDC 2	SS-B/La	0.2	negative
CDC 3	RNP/Sm, SS-A/Ro, SS-B/La	0.2	negative
CDC 4	U-1 RNP	0.3	negative
CDC 5	Sm	0.4	negative
CDC 6	Fibrillarin	0.2	negative
CDC 7	SS-A/Ro	0.1	negative
CDC 8	Centromere	0.2	negative
CDC 9	Scl-70	0.2	negative
CDC 10	Jo-1	0.1	negative
CDC 11	PM/Scl (PM 1)	0.2	negative
CDC 12	Rib-P	5.7	positive

Figure 1
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 Ribosomal P ELISA (REF: 25002). Only the anti-ribosomal P positive sample (CDC 12) was found to be positive.

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Assay performance

- Good correlation to ELISA systems with recombinant or native proteins
- Excellent “lot to lot” correlation $R^2 > 0.95$
- Low intra- and inter-assay variation
- Excellent linearity over the entire range

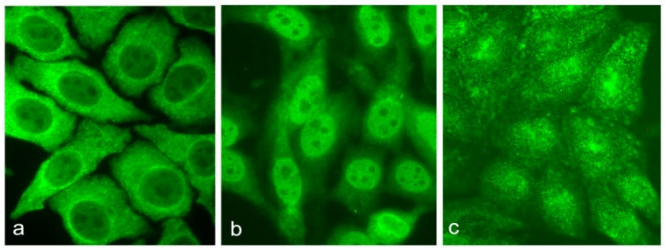
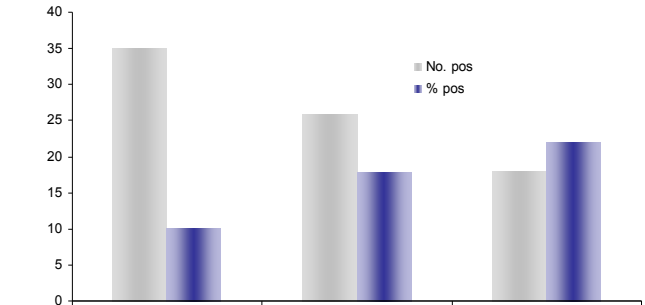


Figure 2
Inter manufacturer variability of anti-ribosomal P IIF staining pattern (CP) produced by monospecific anti-Rib-P serum sample on slides from three different suppliers. (Mahler et al. 2008)



	all	> moderate	> high
No. pos	35	26	18
% pos	10.1	17.9	22

Figure 3
Number and percentage of anti-Rib-P positive samples with CP in all anti-Rib-P positive samples (n=345), moderate and high positives (n=145) and high positives only (n=82).

Cut-off	1 RU	1.5 RU
Sensitivity %	24.1	11.5
Specificity %	100	100

Figure 4
Clinical sensitivity and specificity of the new Ribosomal P ELISA at different cut-off values in a cohort of Caucasian SLE patients, disease controls and healthy donors. The results are in good agreement to reported prevalence in literature.

Ribosomal P ELISA (25002)				
Reference method		neg	pos	
	neg	82	7	89
	pos	4	7	11
		86	33	100

Figure 5
Agreement to a commercial available ELISA. 100 serum samples from SLE patients were tested in the Ribosomal P ELISA (REF: 25002) and in a validated reference method (ALBIA) demonstrating good agreement (89 %, $p < 0.0001$, kappa = 0.5) between the two assays. The sensitivity of the new Ribosomal P ELISA (REF: 25002) was significantly higher. (cut-offs: ALBIA = 350 LU, ELISA = 1.5 RU)

Literature

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2011-05

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