SLE Profile 4 ELISA

The SLE Profile 4 ELISA contibutes to the diagnosis of systemic lupus erythematosus (SLE) and related autoimmune diseases

Circulating antibodies to intracellular 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 (SS-A), La (SS-B), centromere proteins, Scl-70 (topoisomerase I, topo I), the Smith Antigen (Sm), Ribonucleoproteins (RNP), Jo-1 and PM/Scl. Antibodies against dsDNA and the Sm complex rate as highly-specific markers for 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 antibodies they were included as diagnosis criteria of the American College of Rheumatology (ACR). Antibodies against the ribosomal phosphoproteins (Rib-P) can be detected in 10-30% of SLE patients with high disease specificity. Anti-RNP antibodies are considered as SLE associated antibodies which are also found in other inflammatory autoimmune disorders.

The SLE Profile 4 ELISA is intended for the semi-quantitative determination of SLE associated antibodies. Thus results of the SLE Profile 4 ELISA aid to the diagnosis of SLE and related systemic autoimmune diseases.

SLE Profile 4 ELISA Specifications

- Highly purified synthetic, recombinant or native antigensFarbcodierte Reagenzien
- 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
- One calibrator for all parameters
- Also usable for small series with few patients

SLE Profile 4 ELISA REF 25019 96

Table 1
Antigens contained in the test

Antigen	Prevalence	Specificity	Color
dsDNA	20-70%	>90%	yellow
Sm	5-30%	>98%	orange
RNP/Sm	20-40%	low	brown
Rib-P	10-20%	>98%	colorless

Antigene	Sensitivity %	Specificity %
dsDNA[1]	100	100
Sm[2]	11.2	98.4
RNP/Sm[1]	96 - 100	89.5
Rib-P[2]	12 - 20	100

Figure 1
Analytical and clinical sensitivity and specificity of the antigens used in the test. For more information use the product information of the individual tests (REF: 25002, 25005, 25010, 25011) .

Assay performance

- Good correlation to reference ELISA systems
- Excellent "lot to lot" correlation $R^2 > 0.95$
- Low intra- and inter-assay variation
- Excellent linearity over the entire measuring range

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	SLE Profile 4 ELISA (25019)			
Reference		pos	neg	
	pos	50	15	65
	neg	14*	112	126
		64	127	191

Figure 2
Overall agreement of the SLE Profile 4. 191 samples from patients suffering from SLE were tested in the ELISA assays (REF: 25002, 25005, 25010, 25011) and in corresponding validated reference assays. The results show a good agreement of > 85% between the methods.
*One sample tested borderline in the RNP/Sm ELISA (REF: 25011) (RU=1.0)

Figure 3
Microtiter plate of the SLE Profile 4 ELISA with colour coded, breakapart wells. The system has been designed to give the user maximum comfort and easiest handling for most different conditions ranging from automated handling to manual testing of small series of patient´s sera.

Literature

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