



recomLine ANA/ENA IgG

Line immunoassay using recombinant antigens to detect IgG autoantibodies in Connective Tissue Diseases (CTD)

Autoantibodies are immunoglobulins which are directed against endogenous structures. In the case of CTD, the connective tissue is affected, which leads to inflammation, loss of elasticity and joint pain. According to their clinical symptoms, these diseases are assigned to the rheumatic disorders.

The most frequent types of connective tissue diseases are:

- ▶ Systemic lupus erythematosus (SLE)
- ▶ Sjögren's syndrome (SjS)
- ▶ Mixed connective tissue disease (MCTD)
- ▶ Progressive systemic sclerosis (PSS)
- ▶ Myositis

Autoantibodies are important diagnostic parameters with unclear pathogenetic significance, but of extraordinary relevance for differential diagnosis. The *recomLine ANA/ENA IgG* serves for the differentiation between rheumatic autoimmune diseases and other rheumatic diseases with similar symptoms.

Product Advantages

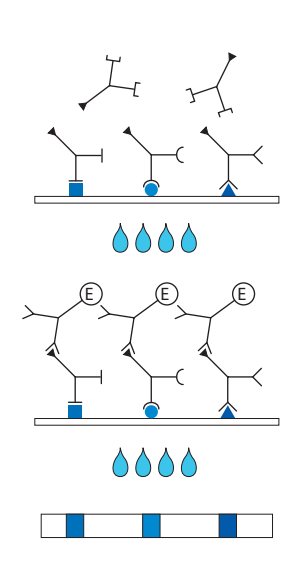
- High sensitivity and specificity ensured by the use of recombinant antigens
- Fast and easy to use due to automation and software based evaluation
- One single approach to differentiate between the most frequent autoimmune collagenose diseases enabled by the use of 15 different antigens
- Highly reliable diagnostic of SLE using subunits of Sm and RNP antigens and high specific SLE markers
- Reliable diagnostic due to internal cut-off-control and IgG control
- Compatible with all other MIKROGEN line assays - reagents exchangeable
- CE label: The *recomLine ANA/ENA IgG* test meets the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices

Recombinant Antigens

Antigen	Natural Function	Size of rec. Antigen [kDa]
RNP68	specific ribonucleoprotein (68 kD), component of spliceosomes	68
RNPA	specific ribonucleoprotein (34 kD), component of spliceosomes	34
RNPC	specific ribonucleoprotein (22 kD), component of spliceosomes	22
SmB	Smith-protein B (28 kD); core-protein of the spliceosomes	28
SmD	Smith-protein D (16 kD); core-protein of the spliceosomes	16
Ro/SSA60	participate in translation of ribosomal mRNA	60
Ro/SSA52	participate in translation of ribosomal mRNA	52
La/SSB	involved in the termination of RNA-polymerase-III-transcription	48
Rib-P	acidic phosphoprotein (15 kD) of ribosomal RNPs necessary for translation	36
PCNA	cyclin und assistant protein of DNA-polymerase delta	36
CENPB	participate in the segregation of the chromosomes in dividing cells	80
Scl70	DNA-topoisomerase I	91
Jo-1	histidyl-tRNA-synthetase	50
Histones	alkaline DNA-binding protein	33
dsDNA	double stranded DNA as a template for mRNA	-



Test Principle and Procedure



1st Incubation A test strip loaded with autoimmune antigens is incubated with diluted serum or plasma in an incubation tray for **1 hour**.

wash 3 times

2nd Incubation Peroxidase conjugated anti-human antibodies (IgG specific) are added. Incubate for **45 minutes**.

wash 3 times

Color reaction Within **8 minutes** after addition of the coloring solution, insoluble colored bands develop at the sites on the test strips occupied by antibodies.

Evaluation

Diagnostic Sensitivity

recomLine ANA/ENA IgG			
Defined sera	total	positive*	sensitivity
SLE	88	84	95 %
SjS	42	42	100 %
PSS	54	54	100 %
MCTD	22	22	100 %
Myositis	20	20	100 %

* Specific for the respective type of collagenase reaction pattern
Diagnostic sensitivity was determined on the basis of defined sera (defined by clinical picture (SLE; BILAG score, n=30) and/or specific antigen pattern confirmed with two comparison tests (n=226).

Sensitivity of Autoantibody detection

recomLine ANA/ENA IgG																
Defined sera	RNP 68	RNP A	RNP C	SmB	SmD	SSA60	SSA52	SSB	Rib-P	PCNA	CenpB	Scl70	Jo-1	Histone	dsDNA	
Number of samples tested [n]*	31	23	21	31	29	28	36	19	16	11	23	12	11	14	38	
sensitivity [%]	93.5	95.6	95.2	90.3	93.1	100	100	100	100	100	100	100	100	92.9	100	

* Sera shown to be positive for the respective marker in two ELISA test systems and one line immunoassay (n=130 sera)

Specificity of Autoantibody detection

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Defined sera	RNP 68	RNP A	RNP C	SmB	SmD	SSA60	SSA52	SSB	Rib-P	PCNA	CenpB	Scl70	Jo-1	Histone	dsDNA	
specificity [%]	100	100	100	100	99.5	98.9	99.5	100	100	99.5	100	100	99.5	98.4	98.9	

The specificity was determined with the following potentially cross-reactive sera or sera specific immunological constitution or sera matrix: autoimmune vasculitis (n = 23), psoriasis (n = 30), EBV IgM (n = 30), blood donor sera (n = 100); n = 183 total

Article-No

6072

recomLine ANA/ENA IgG
Reagents for 20 determinations

Storage

At +2°C - +8°C