





recomLine ANA/ENA IgG

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

Autoantibodies are immunglobulines 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 syndrom (SjS)
- Mixed connective tissue disease (MCTD)
- Progressive systemic scleroderma (PSS)
- Myositis

Autoantibodies are important diagnostic parameters with unclear pathogenetic significance, but of extraordinary relevance for differential diagnosis. The *recom*Line 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 *recom*Line 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 ribosomale mRNA	60
Ro/SSA52	participate in translation of ribosomale 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 assistent 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	-

React. Control

Cut-off-Contr. RNP68

RNPA

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RNPC SmB

SmD

Ro/SSA60

Ro/SSA52

La/SSB

Rib-P

PCNA

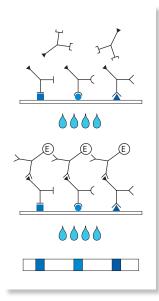
CENPB ScI70

1- 1

Histon

dsDNA

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 speific) are

added. Incubate for 45 minutes.

wash 3 times

Color reaction Within 8 minutes after addition of the coloring solution, insolu-

ble colored bands develop at the sites on the test strips occupied

by antibodies.

Evaluation

Diagnostic Sensitivity

recomLine ANA/ENA lgG												
Defined sera	total	total positive* sens										
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 collagenose 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 lgG															
Defined sera	RNP 68	RNP A	RNP C	SmB	SmD	SSA60	SSA52	SSB	Rib-P	PCNA	CenpB	Scl70	Jo-1	Histone	dsDNA
Number of sam- ples 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

recomLine ANA/ENA lgG															
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

Storage

6072

recomLine ANA/ENA IgG
Reagents for 20 determinations

At +2°C - +8°C