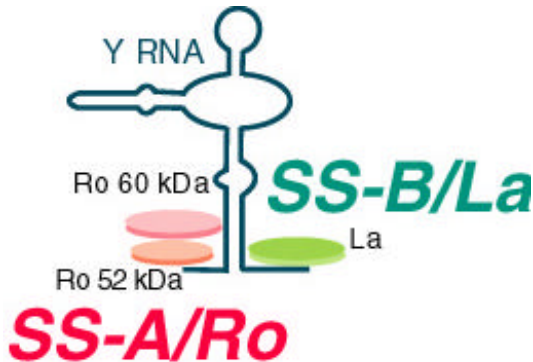


REAADS ANA Test Kit

For In Vitro Diagnostic Use

The REAADS ANA Test Kit is a semi-quantitative enzyme-linked immunosorbent assay (ELISA) for the detection of specific anti-nuclear antibodies in human serum as an aid in the determination of autoimmune diseases.



- Detects autoantibodies to specific nuclear antigens, including RNP, Sm, SSA, SSB, Scl-70, Jo-1, CENP-B, Ribosomal P, DNA and Histones
- Excellent correlation with specific autoantibody ELISA test kits
- Improved specificity compared to immuno-fluorescent assays (IFA)
- Results are reported in semi-quantitative units, eliminating subjective interpretation required with IFA
- Easy to use procedure can be automated allowing for a large number of specimens to be screened in a short period of time

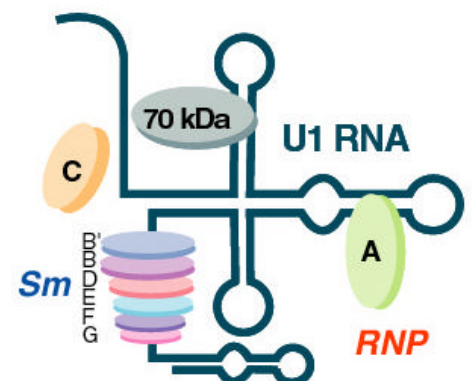
Clinical Performance:

A population of 286 autoimmune patients was tested on the REAADS ANA Test Kit, including SLE (102), MCTD (56), Sjögren's Syndrome (46), Systemic Sclerosis (55) and polymyositis/dermatomyositis (27). Healthy donor samples (38) were also tested as controls. Results are shown in the table on the right. These compare well with the table below.

Disease	Positive rates
SLE	98%
MCTD	94%
SjS	96%
SSc	95%
PM/DM	67%
Healthy	5%

In a separate study, 132 HEp2 IFA positive specimens were tested on the REAADS ANA Test Kit. 111 (84%) resulted positive. Of those positive on the ELISA, 105 (95%) resulted positive on specific autoimmune ELISA assays. 74% of the IFA positive/ELISA negative specimens resulted negative on the specific autoimmune ELISA assays. Results of testing healthy donor populations on the two methods resulted in specificities of 92% with the REAADS ANA Test Kit compared to 64% with HEp2 IFA.

autoantibody	Related autoimmune disease	Frequency
anti-SSA	Sjögren's syndrome	88 - 96%
	SLE	24 - 60%
	PM/scleroderma	5 - 10%
anti-SSB	Sjögren's syndrome	71 - 87%
	SLE	9 - 35%
anti-Sm	SLE	15 - 30%
anti-RNP	MCTD	95 - 100%
	SLE	30 - 40%
	PM/scleroderma	2 - 24%
anti-dsDNA	SLE	40 - 70%
anti-ssDNA	SLE (RA, Sjögrens syndrome)	~80%
	drug induced lupus	~80%
anti-Scl-70	progressive systemic sclerosis	20 - 59%
anti-CENP-B	CREST syndrome (scleroderma)	57 - 82%
anti-Jo-1	polymyositis (w/dermatomyositis -25%)	13 - 43%
anti-Ribosomal P	SLE	5 - 20%



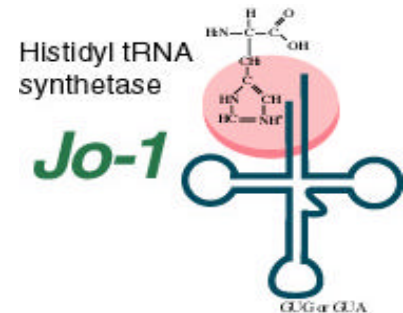
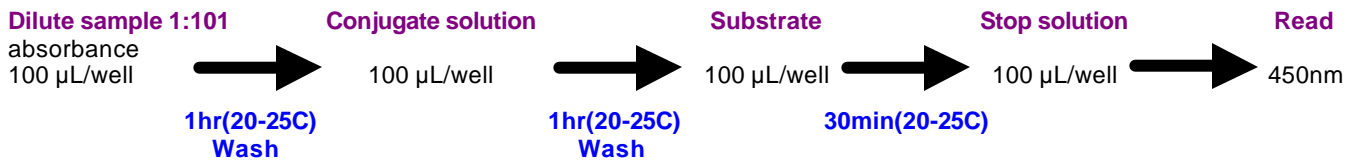
REAAADS ANA Test Kit

For In Vitro Diagnostic Use

Anti-nuclear antibodies (ANA) are autoantibodies against various cell nucleus antigens and some are considered to be useful for diagnosis of autoimmune diseases such as Systemic Lupus Erythematosus (SLE), Mixed Connective Tissue Disease (MCTD), Sjogren's syndrome (SS) and Progressive Systemic Sclerosis (PSS). Indirect immunofluorescence (IF) has been used widely to detect anti-nuclear antibodies. As the corresponding antigen can be presumed by staining pattern, it can yield information on a variety of autoantibody specificities. On the other hand, it is inconvenient when many samples are examined and it sometimes lacks assay specificity due to differences between reagents, operators and laboratory equipment.

The REAAADS ANA ELISA test detects disease specific anti-nuclear antibodies, including anti-RNP, Sm, SSA, SSB, Scl-70, Jo-1, CENP-B, Ribosomal P, DNA and Histones, which are frequently observed in patients with autoimmune diseases. This test makes it possible to use objective judgment since the results are expressed as Index Values. Many samples can be screened in a short period of time.

Assay Procedure



Kit Contents

96 antigen coated microwells in frame	12 x 8 strips
Calibrator-1 (0 U/mL) (ready to use)	1.5 ml
Calibrator-2 (100 U/mL) (ready to use)	1.5 ml
Positive Control	0.2 ml
Negative Control	0.2 ml
Conjugate Concentrate (101x) (HRP conjugated goat anti-human immunoglobulins)	0.3 mL
Conjugated Diluent	24 ml
Assay Diluent	50 ml
Wash Concentrate (10x)	100 ml
Substrate (ready to use)	20 ml
Stop Solution (ready to use)	20 ml

REAAADS ANA Test Kit

Product # 10876

Quantity: 96 tests

Storage: 2-8 C

Stability: 12 months after manufacturing

