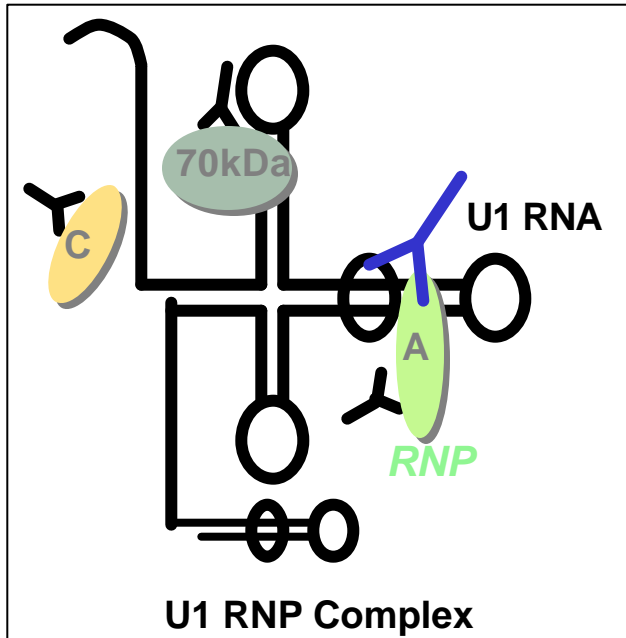


REAADS Anti-RNP Test Kit

For In Vitro Diagnostic Use

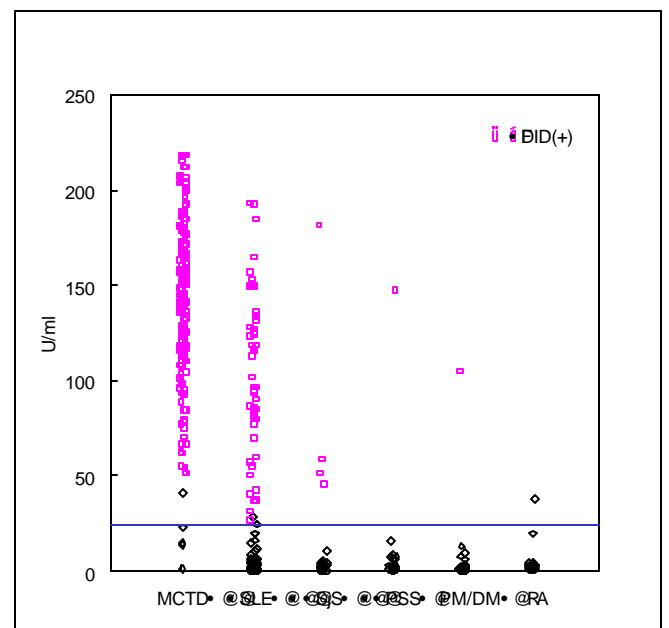
The REAADS anti-RNP Test Kit is a semi-quantitative enzyme-linked immunosorbent assay (ELISA) for the detection of anti-RNP antibodies in human serum as an aid in the determination of certain autoimmune diseases.



- **Increased Sensitivity - Detects additional autoantibodies compared to ELISA's using RNP only**
- **Detects antibodies which recognize the structural configuration of U1 snRNP complex**
- **Correctly coincides with double immunodiffusion and immunoprecipitation assays**
- **Detects anti-U1 RNP autoantibodies independently from anti-Sm antibodies**
- **Increased Specificity – recombinant proteins and peptides as coated antigens providing a high degree of specificity**

Clinical Performance:

A population of 421 autoimmune patients, including 199 Mixed Connective Tissue Disease (MCTD), was tested on the REAADS anti-RNP Test Kit and results were compared to both an ELISA using only RNP proteins (RNP 70kd, A and C) and double immunodiffusion (DID). Results of the Corgenix assay are shown in the figure on the right (positive DID results are also indicated). Increased sensitivity was demonstrated with the REAADS anti-RNP Test Kit containing U1RNA in both the MCTD and SLE population (98% and 42%) compared to the ELISA containing only RNP proteins (91% and 33%). Also, the relative sensitivity of the REAADS anti-RNP Test Kit was higher than the other ELISA compared to DID for the total autoimmune population (99% vs. 95%). A control population of 50 healthy donors was also tested on each ELISA methods resulting in 98% specificity for both assays.



Results from testing autoimmune populations using REAADS anti-RNP Test Kit; Y Takasaki et al., Jpn Med Pharm Sci. 44, 599-609 (2000)

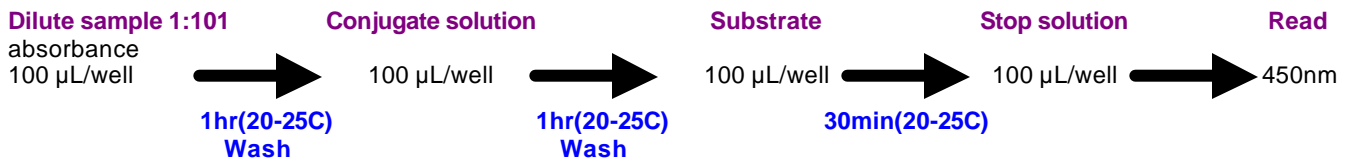
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RNP antibodies are ENA (extractable nuclear antigen) antibodies, present with high frequency in the sera of patients with collagen diseases such as SLE (30 - 40%) and mixed connective tissue disease (MCTD) (95 - 100%). Mixed connective tissue disease is a clinical disease combining features of SLE, Progressive Systemic Sclerosis (PSS) and Polymyositis/Dermatomyositis (PM/DM). The presence of RNP antibodies in the sera of patients is essential for diagnosis of MCTD. RNP antibodies, when present alone at high levels, are diagnostic of MCTD. Lower levels of anti-RNP, in conjunction with other autoantibodies may be observed in PSS, Sjögren's Syndrome (SS) and Rheumatoid Arthritis (RA).

Among the methodologies available to detect anti-ENA's are Immunoblot, Double Immunodiffusion (DID), Immunoprecipitation (IPP) and Enzyme-linked Immunosorbent Assay (ELISA). The ELISA tests are specific, sensitive, and due to their objectivity and rapidity, suitable for testing samples from patients with suspected connective tissue diseases. The REAADS anti-RNP Test Kit uses recombinant protein for the solid phase antigen. Therefore, the test shows specificity for detection of anti RNP antibodies present in high frequency in the sera of patients with certain connective tissue diseases.

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
Conjugated Reagent (ready to use) (HRP conjugated goat anti-human immunoglobulins)	20 ml
Assay Diluent	50 ml
Wash Concentrate (10x)	100 ml
Substrate (ready to use)	20 ml
Stop Solution (ready to use)	20 ml

REAADS anti-RNP Test Kit

Product # 10869

Quantity: 96 tests

Storage: 2-8 C

Stability: 12 months after manufacturing