



Laboratory Service Manual

Lab Dept: Flow and Immunology

Test Name: ANTIBODIES TO EXTRACTABLE NUCLEAR ANTIGENS

General Information

Lab Order Codes: ABENA

Synonyms: ENA antibodies; Anti-ENA

CPT Codes: 86235 x6 – Extractable nuclear antigen, antibody to, any method

Test Includes: Detection of antibodies to the extractable nuclear antigens Sm (Smith), RNP, SS-A (Ro), SS-B (La), Scl-70, and Jo-1 in serum. The results will be reported in ENA Units with corresponding interpretations of negative, borderline or positive.

Logistics

Test Indications:

The results from this assay can be used as an aid in the diagnosis of autoimmune diseases. The incidence of autoantibodies to various nuclear antigens varies depending upon the patient population, and the incidence of clinical rheumatic diseases in that population. The association of the antibodies with specific rheumatic diseases is summarized in this table:

Antibodies to:	Disease Association:
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Sm	Highly specific marker antibody seen in 25 - 30% of SLE patients
U1-RNP	Mixed Connective Tissue Disease >95%; SLE 35%; lower frequency in discoid lupus or progressive systemic sclerosis (PSS).
SS-A/Ro	Sjögren's syndrome 60 - 70%; SLE 50%
SS-B/La	Sjögren's syndrome 40 - 50%; SLE 15%
Scl-70	Highly specific marker antibody seen in 15 - 20% of PSS patients
Jo-1	Highly specific marker antibody seen in 25 - 30% of patients with polymyositis or dermatomyositis

Lab Testing Sections: Immunology

Phone Numbers:

Minneapolis: 612-813-6280

Saint Paul: 651-220-6550

Test Availability: Daily, 24 hours

Turnaround Time: 1 - 4 days – testing is batch processed twice weekly

Special Instructions: N/A

Specimen

Specimen Type: Blood

Container: Red top tube, plain, no gel

Draw Volume: 1.5 mL blood

If ANA and/or dsDNA are also being ordered, a draw volume 1.5 mL will be adequate for all tests.



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Processed Volume:	0.5 mL serum
Collection:	Blood should be collected aseptically and placed in a plain red top tube or other plain sterile tube without anticoagulant and allowed to clot at room temperature.
Special Processing:	Lab Staff: Centrifuge specimen; transfer serum to a plain polypropylene tube, and refrigerate. If testing is delayed longer than 7 days, serum should be frozen at -20°C or colder. Serum should not be stored in a self-defrosting freezer.
Patient Preparation:	N/A
Sample Rejection:	Sera exhibiting a high degree of hemolysis, icterus, or microbial growth will not be used because these conditions may cause aberrant results.

Interpretive

Reference Range:	The results will be reported in ENA Units with corresponding interpretations of negative, borderline or positive: <20 ENA Units: Negative 20 - 30 ENA Units: Borderline >30 ENA Units: Positive
Critical Values:	N/A
Limitations:	Diagnosis cannot be made on the basis of antibodies to extractable nuclear antigens alone. Some patients with autoimmune diseases may have undetectable or insignificant levels of antibodies to extractable nuclear antigens, and some individuals may have high levels of antibodies to extractable nuclear antigens, but little or no evidence of clinical disease. The physician must interpret these results in conjunction with the patient's history and symptoms, the physical findings, and other diagnostic procedures.
Methodology:	Qualitative Indirect Enzyme Immunoassay (EIA)
Contraindications:	See Limitations
References:	Immuno Concepts® RELISA® ENA Test System Package Insert. July 1996