



Laboratory Service Manual

Lab Dept: Flow Cytometry/Immunology

Test Name: REFLEXIVE ANTINUCLEAR ANTIBODY PROFILE

General Information

Lab Order Codes: RAAP

Synonyms: Reflexive ANA Profile

CPT Codes: 86038 – Antinuclear antibodies (ANA)

86039 – ANA titer

86225 – Deoxyribonucleic acid (DNA) antibody; native or double stranded

86235 x6 – Extractable nuclear antigen, antibody to, any method, each antibody

86256 – Fluorescent noninfectious agent antibody; titer

Test Includes: The Fluorescent Antinuclear Antibody Screen,-pattern, and- titer; the Antibodies to Extractable Nuclear Antigen (ENA) Assay; and the ds-DNA Autoantibody Assay are all included in this profile if indicated and will be utilized according to the following testing algorithm.

Reflexive ANA Algorithm

- Negative – **Stop**
 - Positive – ANA titer and Pattern
 - Any positive pattern – Antibodies to ENAs
 - Homogeneous pattern – [dsDNA titer](#) (referred to Mayo)
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Logistics

Test Indications: Antinuclear antibody (ANA) is a general term used to describe autoantibodies against various cell nuclear proteins. The results from this Reflexive Profile 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.

Lab Testing Sections: Immunology



Laboratory Service Manual

Phone Numbers:

Minneapolis: 612-813-6280

Saint Paul: 651-220-6550

Test Availability: Daily, 24 hours, batch processed twice weekly

Turnaround Time: 1 - 4 days – See [Test Availability](#)

Special Instructions: N/A

Specimen

Specimen Type: Whole blood

Container: Red (plain, no gel) top tube

Draw Volume: 1.5 mL blood

Processed Volume: 0.5 mL serum

A total volume 0.5 mL of serum will be adequate for all tests.

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: None

Sample Rejection: Sera exhibiting a high degree of hemolysis, icterus, or microbial growth will not be used because these conditions may cause aberrant results. Mislabeled or unlabeled specimens.

Interpretive



Laboratory Service Manual

Reference Range:

ANA Screen: Negative

ds-DNA Screen: Negative

For more information [see dsDNA](#) test listing.

The ANA will be reported as Negative or Positive. The screening titer is 1:160. If positive, the pattern will also be reported and the serum will be titered.

ENA Assay: <20 ENA Units = Negative

The ENA results will be reported in ENA Units with corresponding interpretations of negative, borderline or positive

Critical Values:

N/A

Limitations:

Diagnosis cannot be made on the basis of antinuclear antibody detection alone. The physician must interpret ANA results in conjunction with the patient's history and symptoms, the physical findings, and other diagnostic procedures.

Methodology:

ANA Screen: Indirect Fluorescent Antibody (IFA) using HEp-2000® substrate

Enzyme-Linked Immunoabsorbent Assay (ELISA)

Qualitative Indirect Enzyme Immunoassay (EIA)

Contraindications:

Patients with heterophile antibodies may give equivocal results. Patients undergoing steroid therapy may have negative results for ds-DNA antibody.

References:

Immuno Concepts® HEp-2000® Fluorescent ANA-Ro Test System Package Insert, February 1998

[Mayo Medical Laboratories Web Page](#) December 2006

Immuno Concepts® RELISA® ENA Test System Package Insert, July 1996