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 (FANA),-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
- Positive Speckled or Homogeneous pattern – Antibodies to ENAs
- Positive Speckled or Homogeneous pattern – dsDNA titer (referred to Mayo)

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 (Mpls Campus)

Phone Numbers: MIN Lab: 612-813-6280

STP Lab: 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:	Blood
Container:	SST-Serum Separator (Marble, gold or red)
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 an SST 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 -20ºC 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

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 2014 Immuno Concepts® RELISA® ENA Test System Package Insert, July 1996
Updates:	12/8/2014: FANA only orderable as part of Reflexive Panel. 4/12/2016: SST tube update.