Overview

Useful For
Evaluating patients suspected of having systemic rheumatic disease

Method Name
Indirect Immunofluorescence

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required
Container/Tube: Serum gel or red top

Specimen Volume: 0.5 mL

Forms
If not ordering electronically, complete, print, and send a General Request (T239) with the specimen.

Specimen Minimum Volume
0.3 mL

Reject Due To

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>OK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross lipemia</td>
<td>OK</td>
</tr>
<tr>
<td>Gross icterus</td>
<td>OK</td>
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</tbody>
</table>

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Serum</td>
<td>Refrigerated (preferred)</td>
<td>21 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>28 days</td>
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Clinical and Interpretive

Clinical Information
Measurement of antinuclear antibodies (ANA) in serum is the most commonly performed screening test for patients suspected of having a systemic rheumatic disease, also referred to as connective tissue disease. (1) ANA occur in patients with a variety of autoimmune diseases, both systemic and organ-specific. They are particularly common in
the systemic rheumatic diseases, which include lupus erythematosus (LE), discoid LE, drug-induced LE, mixed connective tissue disease, Sjogren syndrome, scleroderma (systemic sclerosis), CREST (calcinosclerosis, Raynaud phenomenon, esophageal dysmotility, sclerodactyly, telangiectasia) syndrome, polymyositis/dermatomyositis, and rheumatoid arthritis.(1)

The diagnosis of a systemic rheumatic disease is based primarily on the presence of compatible clinical signs and symptoms. The results of tests for autoantibodies including ANA and specific autoantibodies are ancillary. Additional diagnostic criteria include consistent histopathology or specific radiographic findings. Although individual systemic rheumatic diseases are relatively uncommon, a great many patients present with clinical findings that are compatible with a systemic rheumatic disease and large numbers of tests for ANA are ordered to eliminate the possibility of a systemic rheumatic disease.

Reference Values
<1:80 (Negative)

Interpretation
A large number of healthy individuals have low-titer antinuclear antibody (ANA) results, many of which are likely to be clinical false-positives; therefore, second-order testing of all positive ANAs yields a very low percentage of positive results to the specific nuclear antigens.

A positive ANA result at any level is consistent with the diagnosis of systemic rheumatic disease. Positive ANA results are associated with the presence of detectable autoantibodies to specific nuclear antigens. The nuclear antigens are associated with specific diseases (eg, anti-Scl 70 is associated with scleroderma) and can be detected with second-order testing.

Cautions
Some patients without clinical evidence of an autoimmune disease or a systemic rheumatic disease may have a detectable level of antinuclear antibody (ANA). This finding is more common in women than men and the frequency of a detectable ANA in healthy women over 40 years of age may approach 15% to 20%. ANA may also be detectable following viral illnesses, in chronic infections, or in patients treated with many different medications.

Clinical Reference

Performance

Method Description
Antibodies to nuclear antigens in a human epithelial type 2 (HEp-2) cell line by an indirect immunofluorescent technique. Commercial slides prepared from HEp-2 cells are used as a substrate. IgG antibodies in serum specimens are detected after incubation of serum with the commercial slides by the addition of a fluorescein isothiocyanate (FITC)-labeled antihuman-IgG reagent. All patient specimens are initially screened at 1:80.(Package insert: NOVA Lite ANCA. Inova Diagnostics, San Diego, CA)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Saturday; 11 a.m.

**Analytic Time**
1 day

**Maximum Laboratory Time**
2 days

**Specimen Retention Time**
14 days

**Performing Laboratory Location**
Rochester

**Fees and Codes**

**Fees**
- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact [Customer Service](#).

**Test Classification**
This test has been cleared, approved or is exempt by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

**CPT Code Information**
86039

**LOINC® Information**

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<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<td>NAIFA</td>
<td>Antinuclear Ab, HEp-2 Substrate, S</td>
<td>59069-5</td>
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<table>
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