Overview

Useful For
Evaluating patients with signs and symptoms of a connective tissue disease in whom the test for antinuclear antibodies is positive.

Testing for SS-A/Ro antibodies is not useful in patients without demonstrable antinuclear antibodies.

Testing Algorithm
See Connective Tissue Disease Cascade (CTDC) in Special Instructions.

Special Instructions
- Connective Tissue Disease Cascade (CTDC)

Method Name
MultiplexFlowImmunoassay

NY State Available
Yes

Specimen

Specimen Type
Serum

Specimen Required
Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Specimen Volume: 0.5 mL

Specimen Minimum Volume
0.35 mL

Reject Due To

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>Reject</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross lipemia</td>
<td>Reject</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>
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Clinical and Interpretive

Clinical Information
SS-A/Ro is an extractable nuclear antigen (ENA) composed of protein antigens of 52 kD and 60 kD combined with cytoplasmic RNA species. SS-A/Ro antibodies occur in patients with several different connective tissue diseases including Sjogren syndrome, an autoimmune disease that involves primarily the salivary and lacrimal glands (up to 90% of cases); lupus erythematosus (LE) (40%-60% of cases); and rheumatoid arthritis. SS-A/Ro antibodies are associated with childhood LE, neonatal LE, and with congenital heart block in infants born to mothers with LE.(1,2) SS-A/Ro antibodies have also been reported to be associated with features of extraglandular inflammation in patients with LE including vasculitis, purpura, cytopenias, and adenopathy.

SS-A/Ro is 1 of 4 autoantigens commonly referred to as extractable nuclear antigens (ENA). The other ENA are SS-B/La, RNP, and Sm. Each ENA is composed of 1 or more proteins associated with small nuclear or cytoplasmic RNA species (snRNP) ranging in size from 80 to 350 nucleotides. Antibodies to ENA are common in patients with connective tissue diseases (systemic rheumatic diseases) including LE, mixed connective tissue disease, Sjogren syndrome, scleroderma (systemic sclerosis), and polymyositis/dermatomyositis.

See Connective Tissue Disease Cascade (CTDC) in Special Instructions.

Reference Values
<1.0 U (negative)
> or =1.0 U (positive)

Reference values apply to all ages.

Interpretation
A positive result for SS-A/Ro antibodies is consistent with connective tissue disease, including Sjogren syndrome, lupus erythematosus (LE), or rheumatoid arthritis.

A positive result for SS-A/Ro antibodies in a woman with LE prior to delivery indicates an increased risk of congenital heart block in the neonate.

Cautions
No significant cautionary statements

Clinical Reference


Performance
Method Description
Recombinant SS-A/Ro 52 kD and affinity-purified SS-A/Ro 60 kD antigens are coupled covalently to polystyrene microspheres, which are impregnated with fluorescent dyes to create a unique fluorescent signature. SS-A/Ro antibodies, if present in diluted serum, bind to the SS-A/Ro antigens on the microspheres. The microspheres are washed to remove extraneous serum proteins. Phycoerythrin (PE)-conjugated antihuman IgG antibody is then added to detect IgG anti-SS-A/Ro bound to the microspheres. The microspheres are washed to remove unbound conjugate, and bound conjugate is detected by laser photometry. A primary laser reveals the fluorescent signature of each microsphere to distinguish it from microspheres that are labeled with other antigens, and a secondary laser reveals the level of PE fluorescence associated with each microsphere. Results are calculated by comparing the median fluorescence response for SS-A/Ro microspheres to a 4-point calibration curve. (Package insert: Bioplex 2200 ANA Screen. Bio-Rad Laboratories, Hercules, CA 11/2011)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Saturday; 4 p.m.

Analytic Time
1 day

Maximum Laboratory Time
3 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 or approved 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
86235

LOINC® Information

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<th>Test ID</th>
<th>Test Order Name</th>
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<tbody>
<tr>
<td>SSA</td>
<td>SS-A/Ro Ab, IgG, S</td>
<td>33610-7</td>
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