

Overview

Useful For

Evaluating patients at-risk for connective tissue disease with or without interstitial lung disease

Detection of both anti-SS-A 52 (Ro52) and SS-A 60 (Ro60) antibodies in serum

Testing Algorithm

For more information see [Connective Tissue Disease Cascade](#).

Special Instructions

- [Connective Tissue Disease Cascade](#)

Method Name

Multiplex Flow Immunoassay

NY State Available

No

Specimen

Specimen Type

Serum

Specimen Required

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 0.5 mL

Collection Information: Centrifuge and aliquot serum into plastic vial.

Specimen Minimum Volume

0.35 mL

Reject Due To

| | |
|-----------------|--------|
| Gross hemolysis | Reject |
| Gross lipemia | Reject |
| Gross icterus | OK |

| | |
|-----------------------|--------|
| Heat-treated specimen | Reject |
|-----------------------|--------|

Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---------------|--------------------------|---------|-------------------|
| Serum | Refrigerated (preferred) | 21 days | |
| | Frozen | 21 days | |

Clinical & Interpretive

Clinical Information

SS-A/Ro is an extractable nuclear antigen composed of two distinct antigens of 52 kDa (Ro52) and 60 kDa (Ro60) combined with cytoplasmic RNA species.(1,2) SS-A/Ro (Ro52 and/or Ro60) antibodies occur in patients with several different connective tissue diseases including Sjogren syndrome (SjS), an autoimmune disease that involves primarily the salivary and lachrymal glands, systemic lupus erythematosus (SLE), rheumatoid arthritis, systemic sclerosis (SSc) and idiopathic inflammatory myopathies (IIM).(1-5) SS-A/Ro antibodies are associated with childhood SLE, neonatal SLE, and with congenital heart block in infants born to mothers with SLE.(3-5)

Traditionally, anti-SS-A/Ro antibodies were detected by indirect immunofluorescence assay on HEp-2 substrates and confirmed by immunodiffusion, immunoblot or ELISA, mostly using a mixture of both Ro52 and Ro60 as the antigens.(1) With technological advances in the expression and purification of recombinant proteins, solid-phase immunoassays such as ELISA, CLIA, LIA, ALBIA or autoantigen arrays became available that allow the separate detection of anti-Ro52 and anti-Ro60 antibodies.(2,3) Based on separate determination of Ro52 and Ro60 antibodies, there is substantial evidence that differential associations of these autoantibodies in patients may correlate with specific phenotypes in SLE (neonatal lupus, and fetal atrioventricular blockade), SjS, SSc, IIM, or primary biliary cholangitis.(1-4, 6) SjS patients with antibodies to both Ro52 and Ro60 are characterized by higher prevalence of markers of B-cell hyperactivity and glandular inflammation compared to those with single positivity.(4,6) Although these antibodies are often found together, both autoantibodies have important and distinct diagnostic and predictive attributes and should be distinguished when SS-A/Ro antibody is positive or tested singly.(6)

For more information see [Connective Tissue Disease Cascade](#).

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 may be suggestive of connective tissue disease (CTD) such as Sjogren syndrome, systemic lupus erythematosus (SLE), systemic sclerosis (SSc), inflammatory myopathies especially in patients with anti-synthetase syndrome, CTD-associated with interstitial lung diseases (CTD-ILD), or rheumatoid arthritis.

A positive result for SS-A/Ro antibodies in a woman with SLE prior to delivery may suggest an increased risk of congenital

heart block in the neonate.

Differential testing for Ro52 and Ro60 antibodies in SS-A/Ro positive patients may be useful in the diagnosis of specific CTD clinical subset, disease stratification, and prognosis. Consider testing for Ro52 and Ro60 antibodies (ROPAN / Ro52 and Ro60 Antibodies, IgG, Serum) if the patient is positive for SS-A/Ro.

Cautions

[No significant cautionary statements](#)

Clinical Reference

1. Lee AYS, Reed JH, Gordon TP: Anti-Ro60 and anti-Ro52/TRIM21: Two distinct autoantibodies in systemic autoimmune diseases. *J Autoimmun.* 2021 Nov;124:102724. doi: 10.1016/j.jaut.2021.102724
2. Armagan B, Robinson SA, Bazoberry A, et al: Antibodies to both Ro52 and Ro60 for identifying Sjogren's syndrome patients best suited for clinical trials of disease-modifying therapies. *Arthritis Care Res (Hoboken).* 2021 Mar 20;10.1002/acr.24597. Epub ahead of print.
3. Homburger H, Larsen S: Detection of specific antibodies. In: Rich R, Fleisher T, Schwartz B, et al, eds. *Clinical Immunology: Principles and Practice.* 1st ed. Mosby-Year Book; 1996:2096-2109
4. Kotzin B, West S: Systemic lupus erythematosus. In: Rich R, Fleisher T, Shearer W, et al, eds. *Clinical Immunology Principles and Practice.* 2nd ed. Mosby-Year Book; 2001:60.1-60.24

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, 02/2019)

PDF Report

No

Day(s) Performed

Monday through Friday, Sunday

Report Available

1 to 3 days

Specimen Retention Time

14 days

Performing Laboratory Location

Jacksonville

Fees & 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 account representative. For assistance, contact [Customer Service](#).

Test Classification

This test has been cleared, approved, or is exempt by the US 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

| Test ID | Test Order Name | Order LOINC® Value |
|---------|--------------------|--------------------|
| SSA | SS-A/Ro Ab, IgG, S | 33610-7 |

| Result ID | Test Result Name | Result LOINC® Value |
|-----------|--------------------|---------------------|
| SSA | SS-A/Ro Ab, IgG, S | 33610-7 |