

Overview

Useful For

Detection of anti-SSA 52 (Ro52) or SSA 60 (Ro60) antibodies in serum

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

Differentiation of antibodies to Ro52 and Ro60 in patients known to be positive for anti-SSA (Ro) antibodies

Profile Information

| Test Id | Reporting Name | Available Separately | Always Performed |
|---------|-----------------------|----------------------|------------------|
| RO52 | Ro52 Antibody, IgG, S | Yes | Yes |
| RO60 | Ro60 Antibody, IgG, S | Yes | Yes |

Highlights

For the differentiation of Sjogren syndrome (SS)A (Ro52 or Ro60) antibodies in patients at-risk for autoimmune connective tissue disease with or without lung involvement.

Method Name

Chemiluminescent Immunoassay

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Supplies: Sarstedt 5 mL Aliquot Tube (T914)

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container: Plastic vial

Specimen Volume: 1 mL

Collection Instructions: Centrifuge and aliquot serum into plastic vial

Specimen Minimum Volume

0.8 mL

Reject Due To

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

Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---------------|--------------------------|---------|-------------------|
| Serum | Refrigerated (preferred) | 14 days | |
| | Frozen | 21 days | |

Clinical & Interpretive**Clinical Information**

Anti-SS-A (Ro) antibodies can occur in patients with a variety of connective tissue diseases including Sjogren syndrome (SS), systemic lupus erythematosus (SLE), systemic sclerosis (SSc), and idiopathic inflammatory myopathy (IIM).(1) In addition, children born to mothers positive for anti-SS-A/Ro antibodies are at increased risk for congenital heart block.(2)

Anti-SS-A/Ro antibodies can be specific for protein antigens of 52 kDa (Ro52) or 60 kDa (Ro60); these antigens arise from different genes and have unique biological features. The Ro52 antigen is also known as TRIM21; this protein has E3 ligase activity and functions in the process of ubiquitination. The Ro60 antigen is a 60-kDa RNA-binding protein, known to have repair functions for misfolded RNA.(2)

Individuals may display antibody reactivity to either Ro52, Ro60, or both. Patients with only anti-Ro52 antibodies display a higher incidence of IIM and SSc. Anti-Ro52 antibodies in conjunction with antisynthetase antibodies such Jo-1 (others include PL-7, PL-12, EJ, and OJ) are highly associated with interstitial lung disease in patients with IIM. In contrast, isolated anti-Ro60 antibodies are associated with increased risk for SLE and, to a lesser degree, for SS. Positivity for both anti-Ro52 and anti-Ro60 antibodies are most strongly associated with SS; this association is even stronger if anti-SS-B/La antibodies are also detected. The presence of anti-Ro52 and anti-Ro60 antibodies may also be observed in patients with SLE.(3,4)

Reference Values

Ro52 ANTIBODY, IgG

<20 CU (negative)

> or =20 CU (positive)

Reference values apply to all ages

Ro60 ANTIBODY, IgG

<20 CU (negative)

> or =20 CU (positive)

Reference values apply to all ages

Interpretation

The presence of antibodies to both SSA 52 (Ro52) or SSA 60 (Ro60) is highly suggestive of a diagnosis of Sjogren syndrome (SS) with positivity for R060 alone more likely to be associated with systemic lupus erythematosus (SLE).

Antibodies to Ro52 may be present in patients with idiopathic inflammatory myopathy (IIM), systemic sclerosis (SSc) or overlap connective tissue disease (CTD). In CTD, antibodies to Ro52 alone or in association with other specific autoantibodies may be associated with interstitial lung diseases.

Negative results for antibodies to Ro52 and Ro60 does not exclude the possibility of any CTD, including SS, SLE, SSc, and IIM.

Cautions

Results from this testing should be interpreted in the context of clinical findings and other laboratory testing. Tests cannot be exclusively relied upon to establish a diagnosis for any connective tissue disease or related disorder, including systemic lupus erythematosus, Sjogren syndrome (SS), systemic sclerosis, or idiopathic inflammatory myopathy.

When assessed by standard SS-A (Ro) solid phase immunoassays such as enzyme immunoassays using combined antigens, some antibodies specific for either SSA 52 (Ro52) or SSA 60 (Ro60) may not be detected, due to masking of target epitopes. In addition, multiplex bead assays with Ro52 or Ro60 antigens may simply be reported as SS-A/Ro positive without differentiation of the specific positive antibody.

Clinical Reference

1. Fayyaz A, Kurien BT, Scofield H: Autoantibodies in Sjogren's syndrome. *Rheum Dis Clin North Am.* 2016;42(3):419-434
2. Defendenti C, Atzeni F, Spina MF, et al: Clinical and laboratory aspects of Ro/SSA-52 autoantibodies. *Autoimmun Rev.* 2010;10(3):150-154
3. Robbins A, Hentzien M, Toquet S, et al: Diagnostic utility of separate anti-Ro60 and anti-Ro52/TRIM21 antibody detection in autoimmune diseases. *Front Immunol.* 2019 Mar 12;10:444
4. Schulte-Pelkum J, Fritzler M, Mahler M: Latest update on the Ro/SS-A autoantibody system. *Autoimmun Rev.* 2009;8(7):632-637

Performance

Method Description

Paramagnetic beads are coated with purified recombinant Ro52 protein or purified recombinant Ro60 protein. The serum sample is diluted in assay buffer and incubated with the beads. Antibodies to Ro52 or Ro60 bind to their respective beads and are detected by anti-human IgG antibody conjugated with isoluminol. With addition of trigger reagents, a luminescent reaction is produced by the isoluminol conjugate. The light produced by the reaction is measured by a photomultiplier, proportional to the amount of antibodies that are bound to the beads. The antibodies are quantified according to the working curve on the instrument. Anti-Ro52 and anti-Ro60 are reported in

Chemiluminescent Units (CU) as derived from the relative light units measured from each sample. (Package insert: QUANTA Flash Ro52 Reagents, Inova Diagnostics; 06/2019; QUANTA Flash Ro60 Reagents, Inova Diagnostics; 06/2019)

PDF Report

No

Day(s) Performed

Monday, Wednesday, Friday

Report Available

1 to 3 days

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

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 Regional Manager. 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 x 2

LOINC® Information

| Test ID | Test Order Name | Order LOINC® Value |
|---------|----------------------------------|--------------------|
| ROPAN | Ro52 and Ro60 Antibodies, IgG, S | 33610-7 |

| Result ID | Test Result Name | Result LOINC® Value |
|-----------|-----------------------|---------------------|
| RO52 | Ro52 Antibody, IgG, S | 53017-0 |
| RO60 | Ro60 Antibody, IgG, S | 53019-6 |