

## Overview

### Useful For

Evaluating patients with clinical features or at-risk for connective tissue disease, especially Sjögren syndrome.

### Testing Algorithm

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

### Special Instructions

- [Connective Tissue Disease Cascade](#)

### Method Name

Multiplex Flow Immunoassay

### NY State Available

Yes

## 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 Instructions:** Centrifuge and aliquot serum into a plastic vial.

### Specimen Minimum Volume

0.35 mL

### Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	OK
Heat-treated	Reject

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**Specimen Stability Information**

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

**Clinical & Interpretive****Clinical Information**

Sjogren syndrome (SjS) is a heterogeneous systemic autoimmune rheumatic disorder characterized by diverse immunologic responses to SS-A/Ro and SS-B/La antigens.(1) These immune reactivities have been implicated in the destruction of the epithelium of the exocrine glands with the demonstration of typical peri-epithelial lymphocytic infiltration that can vary from sicca syndrome to systemic disease and lymphoma.(2) The SS-A/Ro and SS-B/La system is considered as a heterogeneous antigenic complex which is made up of three different proteins (Ro52, Ro60 and La) and four small RNAs particles.(1,2) The SS-B/La antigen is a 48 kDa phosphorylated protein which can be found in the nucleus and the cytoplasm and binds to several RNA molecules.(3) SS-B/La appears to be susceptible to proteolysis and degrades into smaller but immunoreactive polypeptides.(4)

Unlike antibodies to SS-A/Ro that are present in SjS and other connective tissue diseases (CTD) [systemic lupus erythematosus, systemic sclerosis, inflammatory myopathies, overlap CTD] and primary biliary cholangitis, anti-SS-B/La antibodies are found primarily in patients with SjS.(2,5,6) In addition, SS-A/Ro antibodies may be found alone in many patients with SjS, however, anti-SS-B/La autoantibodies without SS-A/Ro has limited significant association for SjS diagnosis or phenotypic categorization.(2,6,7) Lastly, whereas testing for anti-SS-A/Ro antibodies is included in the 2016 American College of Rheumatology/European League Against Rheumatism classification criteria for primary SjS, evaluation of anti-SS-B/La antibodies is not required.(8)

In a recent multicenter study of more than 10,500 patients with primary SjS, anti-SSB/La antibodies were detected in 58% of anti-SSA/Ro antibody-positive cases.(9) Anti-SS-B/La antibodies are detected using a variety of solid-phase (eg, plate, bead, or membrane) immunoassays such as enzyme-linked immunosorbent assay, fluorometric enzyme-linked immunoassays, chemiluminescence immunoassays, addressable laser bead immunoassay particle-based multianalyte technology and dot or line immunoassays.(10)

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 anti-SS-B/La antibodies may be suggestive of a diagnosis of primary or secondary connective tissue disease including Sjogren syndrome if compatible autoantibody profile and clinical symptoms are present. The positive predictive value for primary Sjogren syndrome is increased with positivity for antibodies to Ro52, Ro60, and SS-B/La. Combination of anti-SSB-B/A and anti-Ro52 and/or anti-Ro60 antibodies may also be useful in the phenotypic

stratification of patients with primary Sjogren syndrome.

### Cautions

Low levels and/or single positivity for anti-SS-B/La antibodies are likely to have limited clinical significance for the diagnosis and phenotypic stratification of patients with primary Sjogren syndrome.

### Clinical Reference

1. Brito-Zeron P, Baldini C, Bootsma H, et al. Sjogren syndrome. *Nat Rev Dis Primers*. 2016;2:16047
2. Vilchez-Oya F, Balastegui Martin H, Garcia-Martinez E, Corominas H. Not all autoantibodies are clinically relevant. Classic and novel autoantibodies in Sjogren's syndrome: A critical review. *Front Immunol*. 2022;13:1003054
3. Bachman M, Mayet WJ, Shroder HC, Pfeifer K, Meyer zum Buschenfelde KH, Muller WE. Association of La and Ro antigens with intracellular structures in HEp-2 carcinoma cells. *Proc Natl Acad Sci U S A*. 1986;83(20):7770-7774
4. Habets WJ, den Brok JH, Boerbooms AM, van de Putte LB, van Venrooij WJ. Characterization of the SS-B (La) antigen in adenovirus-infected and uninfected HeLa cells. *EMBO J*. 1983;2(10):1625-1631
5. Deroo L, Achten H, De Boeck K, et al. The value of separate detection of anti-Ro52, anti-Ro60 and anti-SSB/La reactivities in relation to diagnosis and phenotypes in primary Sjogren's syndrome. *Clin Exp Rheumatol*. 2022;40(12):2310-1317
6. Baer AN, McAdams DeMarco M, Shiboski SC, et al. The SSB-positive/SSA-negative antibody profile is not associated with key phenotypic features of Sjogren's syndrome. *Ann Rheum Dis*. 2015;74(8):1557-1561
7. Acar-Denizli N, Horvath IF, Mandl T, et al. Systemic phenotype related to primary Sjogren's syndrome in 279 patients carrying isolated anti-La/SSB antibodies. *Clin Exp Rheumatol*. 2020;38 Suppl 126(4):85-94
8. Shiboski CH, Shiboski SC, Seror R, et al. 2016 American College of Rheumatology/European League Against Rheumatism classification criteria for primary Sjogren's syndrome: A consensus and data-driven methodology involving three international patient cohorts. *Ann Rheum Dis*. 2017;76(1):9-16
9. Brito-Zeron P, Acar-Denizlin N, Ng WF et al. How immunological profile drives clinical phenotype of primary Sjogren's syndrome at diagnosis: analysis of 10,500 patients (Sjogren Big Data Project). *Clin Exp Rheumatol*. 2018;36(Suppl. 112):S102-112
10. Bossuyt X, De Langhe E, Borghi MO, Meroni PL. Understanding and interpreting antinuclear antibody tests in systemic rheumatic diseases. *Nat Rev Rheumatol*. 2020;16(12):715-726

### Performance

#### Method Description

Affinity-purified SS-B antigen is coupled covalently to polystyrene microspheres, which are impregnated with fluorescent dyes to create a unique fluorescent signature. SS-B/La antibodies, if present in diluted serum, bind to the SS-B antigen 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-B/La 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-B/La microspheres to a 4-point calibration curve. (Package insert: Bioplex 2200 ANA Screen. Bio-Rad Laboratories; 02/2019)

### PDF Report

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No

**Day(s) Performed**

Monday through Saturday

**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 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
SSB	SS-B/La Ab, IgG, S	33613-1

Result ID	Test Result Name	Result LOINC® Value
SSB	SS-B/La Ab, IgG, S	33613-1