

## Overview

### Useful For

Evaluating patients with signs and symptoms of scleroderma and other connective tissue diseases in whom the test for antinuclear antibodies is positive

Testing for Scl 70 antibodies are **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

0.4 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)	21 days	

Specimen Type	Temperature	Time	Special Container
	Frozen	21 days	

## Clinical and Interpretive

### Clinical Information

Scl 70 (topoisomerase 1) is a 100-kD nuclear and nucleolar enzyme. Scl 70 antibodies are considered to be specific for scleroderma (systemic sclerosis) and are found in up to 60% of patients with this connective tissue disease. Scl 70 antibodies are more common in patients with extensive cutaneous involvement and interstitial pulmonary fibrosis, and are considered a poor prognostic sign.(1,2)

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 test result for Scl 70 antibodies is consistent with a diagnosis of scleroderma.

### Cautions

No significant cautionary statements

### Clinical Reference

1. Homburger H, Larsen S: Detection of specific antibodies. In Clinical Immunology: Principles and Practice. First edition. Edited by R Rich, T Fleisher, B Schwartz, et al. St. Louis, Mosby-Year Book, Inc, 1996, pp 2096-2109

2. White B: Systemic sclerosis. In Clinical Immunology Principles and Practice. Second edition. Edited by R Rich, T Fleisher, W Shearer, et al. St. Louis, Mosby-Year Book, 2001, pp 64.1-64.10

## Performance

### Method Description

Recombinant Scl 70 antigen is bound to polystyrene microspheres, which are impregnated with fluorescent dyes to create a unique fluorescent signature. Scl 70 antibodies, if present in diluted serum, bind to the Scl 70 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-Scl 70 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 median fluorescence response for Scl 70 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**

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**

86235

**LOINC® Information**

Test ID	Test Order Name	Order LOINC Value
SCL70	Scl 70 Ab, IgG, S	47322-3

Result ID	Test Result Name	Result LOINC Value
SCL70	Scl 70 Ab, IgG, S	47322-3