

Overview

Reflex Tests

| Test Id | Reporting Name        | Available Separately | Always Performed |
|---------|-----------------------|----------------------|------------------|
| FANTP   | ANA Titer and Pattern | No                   | No               |
| FCA70   | Repeat Anti Scl-70    | No                   | No               |

Testing Algorithm

If Anti-Scl-70 Ab is >=20, Repeat Anti Scl-70 Is performed at an additional charge. If Anti-Nuclear Ab by IFA is positive, reflex test ANA Titer and Pattern is added at no additional charge.

Method Name

RIPA Gel Radiography  
Immunofluorescence Antibody  
Enzyme-linked immunosorbent assay (ELISA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

**Collection Container/Tube:** 10 mL Red  
**Submission Container/Tube:** Plastic vial  
**Specimen Volume:** 3 mL  
**Acceptable:** SST  
**Collection Instructions:** Draw blood in a plain red-top tube(s), serum gel tube is acceptable. Spin down and send 3 mL of serum refrigerated in a plastic vial.

Specimen Minimum Volume

1 mL (volume does **not** allow for repeat testing)

Reject Due To

|                  |                  |
|------------------|------------------|
| Gross hemolysis: | Reject           |
| Thawing:         | Warm OK; Cold OK |

|                |  |
|----------------|--|
| Gross lipemia: | Reject   |
| Gross icterus  | Reject   |
| Other:         | Anything other than serum; bacterial contamination |

Specimen Stability Information

| Specimen Type | Temperature              | Time    | Special Container |
|---------------|--------------------------|---------|-------------------|
| Serum         | Refrigerated (preferred) | 14 days |                   |
|               | Ambient                  | 7 days  |                   |
|               | Frozen                   | 60 days |                   |

Clinical & Interpretive

Clinical Information

Anti-U1 RNP Abs can be found in 2-14% of limited SSC and 5% of diffuse SSc. They are associated with isolated pulmonary arterial hypertension, arthritis and esophageal dysfunction. Anti-Th/To Abs are present in 2-6% of patients with limited SSc and are rarely found in diffuse SSc. They have specificity and are associated with isolated pulmonary arterial HTN, pulmonary fibrosis and renal crisis.

Anti-U3 RNP (Fibrillarin) Abs are highly specific for diffuse SSc with a sensitivity of 4-10%. They are associated with isolated arterial hypertension, myositis, renal and cardiac manifestations of SSc.

Anti-PM/SCL Abs are found in 25% of Scleroderma/myositis overlap, 10% of idiopathic inflammatory myopathy and 2% of Scleroderma cutaneous changes and ILD.

Anti-RNA Polymerase III Abs are useful in the diagnosis of SSc and for the identification of patients at risk for developing renal crisis, progressive skin thickening and cancer. The prevalence of IgG RNAP III antibodies is 20-35% in diffuse SSC and 9% in limited SSc.

Reference Values

Anti-Nuclear Ab by IFA, Anti-U3 RNP(Fibrillarin), Anti-Th/To Ab:  
Reference Range: Negative

Anti-Centromere Ab:  
Reference Range: <1:40

Anti-SCL-70 Ab:  
Reference Range: <20

Anti-RNA Polymerase III, Anti-U1RNP Ab, and Anti-PM/Scl-100 Ab:  
Reference Range: <20  
Negative: <20 units  
Weak Positive: 20-39 units  
Moderate Positive: 40-80 units  
Strong Positive: >80 units

Performance

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

14 to 25 days

Performing Laboratory Location

Esoterix Endocrinology

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 was developed and its performance characteristics determined by LabCorp. It has not been cleared or approved by the Food and Drug Administration.

CPT Code Information

86038  
83516  
86235 x 5  
86256

LOINC® Information

| Test ID | Test Order Name          | Order LOINC® Value |
|---------|--------------------------|--------------------|
| FSCPR   | Scleroderma Comp Profile | Not Provided       |

| Result ID | Test Result Name          | Result LOINC® Value |
|-----------|---------------------------|---------------------|
| Z5784     | Anti-Nuclear Ab by IFA    | Not Provided        |
| Z5785     | Anti-Centromere Ab        | Not Provided        |
| Z5786     | Anti-RNA Polymerase III   | Not Provided        |
| Z5787     | Anti-Scl-70 Ab            | Not Provided        |
| Z5788     | Anti-U1 RNP Ab            | Not Provided        |
| Z5789     | Anti-U3 RNP (Fibrillarin) | Not Provided        |

|       |                    |              |
|-------|--------------------|--------------|
| Z5790 | Anti-Th/To Ab      | Not Provided |
| Z5791 | Anti-PM/Scl-100 Ab | Not Provided |