MAYO CLINIC LABORATORIES

Test Definition: FSCPR

Scleroderma Comprehensive Profile

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