

Systemic Sclerosis Criteria Panel, Serum

Test ID: SSCP

Useful for:

Evaluating patients with antinuclear antibody-associated connective tissue disease, specifically systemic sclerosis

Profile Information:

Test ID	Reporting Name	Available Separately	Always Performed
NAIFA	Antinuclear Ab, HEp-2 Substrate, S	Yes	Yes
SCL70	Scl 70 Ab, IgG, S	Yes	Yes
RNAP	RNA Polymerase III Ab, IgG, S	Yes	Yes

Methods:

NAIFA: Indirect Immunofluorescence

SCL70: Multiplex Flow Immunoassay

RNAP: Enzyme-Linked Immunosorbent Assay (ELISA)

Reference Values:

ANTINUCLEAR ANTIBODIES, HEp-2 SUBSTRATE, IgG
<1:80 (Negative)

Scl 70 ANTIBODIES, IgG
<1.0 U (negative)
> or = 1.0 U (Positive)

RNA POLYMERASE III ANTIBODIES, IgG
<20.0 U (Negative)
20.0-39.9 U (Weak positive)
40.0-80.0 U (Moderate positive)
>80.0 U (Strong positive)

Specimen Requirements:

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)

Preferred: Serum gel

Acceptable:	Red top
Submission Container/Tube:	Plastic vial
Specimen Volume:	0.7 mL
Collection Instructions:	Centrifuge and aliquot serum into a plastic vial.
Minimum Volume:	0.5 mL

Specimen Stability Information:

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

Cautions:

Some patients without clinical evidence of systemic autoimmune rheumatic disease (SARD) may be positive for antinuclear antibody. This occurs at variable prevalence depending on the patient demographics. A positive result may also precede clinical manifestation of SARD or be associated with some viral or chronic infections, cancers, or use of certain medications. All results must be reported in the appropriate clinical context as the performance of the test can be variable.

Low positive Scl-70 antibody results should be interpreted with a high degree of suspicion. Anti-Scl-70 antibodies have been reported in some inflammatory conditions and other connective tissue diseases, especially in patients with systemic lupus erythematosus. A positive result indicates detectable anti-RNA polymerase III above assay cutoff and does not unequivocally establish a diagnosis of systemic sclerosis (SSc).(6,7)

Enzyme immunoassay to detect anti-RNA polymerase III antibody uses an immunodominant epitope as antigen. Negative result does not also rule out the presence of antibodies targeting other epitopes in the RNA polymerase complex.

The level of RNA polymerase III autoantibodies does not indicate the severity of disease in patients with SSc. However, patients with high positive anti-RNA polymerase III antibody titers are more likely to have SSc compared to those with low antibodies.(7)

Anti-RNA polymerase III antibodies may occur prior to clinical onset of SSc.(7)

The presence of immune complexes or other immunoglobulin aggregates in the patient specimen may cause an increased level of nonspecific binding and produce false-positive results with this assay.

CPT Code:

86039
86235
83516

Day(s) Performed: Tuesday, Thursday

Report Available: 2 to 7 days

Questions

Contact Amy Ennis, Laboratory Resource Coordinator at 800-533-1710.