

TEST CHANGE

Criteria Systemic Sclerosis Panel

3000479, SSC PANEL

Specimen Requirements:

Patient Preparation:

Collect: Serum separator tube (SST).

Specimen Preparation: Separate from cells ASAP or within 2 hours of collection. Transfer 3 mL serum to an ARUP standard transport tube. (Min: 1.50-25 mL)

Transport Temperature: Refrigerated.

Unacceptable Conditions: Contaminated, hemolyzed, or severely lipemic specimens.

Remarks:

Stability: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 month (avoid repeated freeze/thaw cycles)

Methodology: Semi-Quantitative Indirect Fluorescent Antibody (IFA) / Semi-Quantitative Multiplex Bead Assay / Semi-Quantitative Enzyme-Linked Immunosorbent Assay (ELISA)

Note:

CPT Codes: 86039; 86235; 83516

New York DOH Approval Status: This test is New York DOH approved.

Interpretive Data:

Component	Interpretation
Scleroderma (Scl-70) (ENA) Antibody, IgG	29 AU/mL or less: Negative 30-40 AU/mL: Equivocal 41 AU/mL or greater: Positive
RNA Polymerase III Antibody, IgG	19 Units or less: Negative 20-39 Units: Weak 40-80 Units: Moderate 81 Units or greater: Strong Positive

Reference Interval:

Test Number	Components	Reference Interval
	<u>Antinuclear Antibody (ANA), HEp-2, IgG</u>	<u>Less than 1:80</u>
	RNA Polymerase III Antibody, IgG	19 Units or less
	Scleroderma (Scl-70) (ENA) Antibody, IgG	40 AU/mL or less



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and its Department of Pathology*

Effective Date: **January 20, 2026**