TEST CHANGE

Scleroderma (Scl-70) (ENA) Antibody, IgG

0050599, SCLER

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube.
Specimen Preparation:	Separate serum from cells ASAP or within 2 hours of collection. Transfer 1 mL serum to an ARUP Standard Transport Tube. (Min: 0.2 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma or other body fluids. Contaminated, hemolyzed, or severely lipemic specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)
Methodology:	Semi-Quantitative Multiplex Bead Assay
Performed:	Sun-Sat
Reported:	1-32 days
Note:	
CPT Codes:	86235
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

The presence of Scl-70 antibodies (also referred to as topoisomerase I, topo-I or ATA) is considered diagnostic for systemic sclerosis (SSc). Scl-70 antibodies alone are detected in about 20 percent of SSc patients and are associated with the diffuse form of the disease, which may include specific organ involvement and poor prognosis. Scl-70 antibodies have also been reported in a varying percentage of patients with systemic lupus erythematosus (SLE). Scl-70 (topo-1) is a DNA binding protein and anti-DNA/DNA complexes in the sera of SLE patients may bind to topo-I, leading to a false-positive result. The presence of Scl-70 antibody in sera may also be due to contamination of recombinant Scl-70 with DNA derived from cellular material used in immunoassays. Strong clinical correlation is recommended if both Scl-70 and dsDNA antibodies are detected.

Negative results do not necessarily rule out the presence of SSc. If clinical suspicion remains, consider further testing for centromere, RNA polymerase III and U3-RNP, PM/Scl, or Th/To antibodies.

Reference Interval:

29 AU/mL or less	Negative
30-40 AU/mL	Equivocal
41 AU/mL or greater	Positive