

TEST CHANGE

Comprehensive Systemic Sclerosis Panel

3000480, SCL COMPRE

Specimen Requirements:

Patient Preparation:

Collect: Serum ~~separator tube~~ **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**. ~~Standard Transport Tube~~. (Min: 1.5 mL)

Transport Temperature: Refrigerated. Also acceptable: Room temperature or frozen.

Unacceptable Conditions: Hemolyzed, hyperlipemic, icteric, heat-treated, or contaminated specimens

Remarks:

Stability: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 month

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

Note: Panel includes: Antinuclear Antibody (ANA) with HEp-2 Substrate, IgG by IFA, Scleroderma (Scl-70) (ENA) Antibody, IgG, RNA Polymerase III Antibody, IgG, Smith/RNP (ENA) Antibody, IgG, Fibrillarin (U3 RNP) Antibody, IgG, PM/Scl-100 Antibody, IgG by Immunoblot.

CPT Codes: 86039; 86235 x4; 83516

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

Interpretive Data:

~~Refer to report.~~ **Refer to report.**

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

| 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 |
| Smith/RNP (ENA) Antibody, IgG | 29 AU/mL 19 Units or less: Negative 30-20 39 Units Weak Positive 40 AU/mL: Equivocal 41 AU/mL-80 Units Moderate |

| | |
|----------------------------------|--|
| | Positive 81 Units or greater: Strong Positive |
| RNA Polymerase III Antibody, IgG | 19 Units or less: Negative 20-39 Units Weak: Positive 40-80 Units Moderate: Positive 81 Units or greater: Strong Positive |

Reference Interval:

| Test Number | Components | Reference Interval |
|-------------|--|---|
| | Antinuclear Antibody (ANA), HEp-2, IgG | Less than 1:80 |
| | Fibrillarin (U3 RNP) Ab, IgG | Negative |
| | PM/Scl 100 Antibody, IgG | Negative |
| | RNA Polymerase III Antibody, IgG | 19 Units or less |
| | Scleroderma (Scl-70) (ENA) Antibody, IgG | 40 AU/mL or less |
| | Smith/RNP (ENA) Ab, IgG | 40 AU/mL 19 Units or less |