

| Procedure | Result | Units | Ref Interval | Accession | Collected | Received | Reported/Verified |
|--|--------------------|-------|-----------------|---------------|--------------------|--------------------|--------------------|
| Double-Stranded DNA (dsDNA) Ab IgG ELISA | Detected * | | [None Detected] | 18-289-900151 | 16-Oct-18 15:16:00 | 16-Oct-18 15:16:00 | 16-Oct-18 15:27:09 |
| Double-Stranded DNA (dsDNA) Ab IgG IFA | 1:10 * | | [<1:10] | 18-289-900151 | 16-Oct-18 15:16:00 | 16-Oct-18 15:16:00 | 16-Oct-18 15:27:50 |
| Smith (ENA) Antibody, IgG | 2 | AU/mL | [0-40] | 18-289-900151 | 16-Oct-18 15:16:00 | 16-Oct-18 15:16:00 | 16-Oct-18 15:27:09 |
| SSA-52 (Ro52) (ENA) Antibody, IgG | 60 H | AU/mL | [0-40] | 18-289-900151 | 16-Oct-18 15:16:00 | 16-Oct-18 15:16:00 | 16-Oct-18 15:27:09 |
| SSA-60 (Ro60) (ENA) Antibody, IgG | 52 H | AU/mL | [0-40] | 18-289-900151 | 16-Oct-18 15:16:00 | 16-Oct-18 15:16:00 | 16-Oct-18 15:27:09 |
| Ribonucleic Protein (U1) (ENA) Ab, IgG | 10 | AU/mL | [0-40] | 18-289-900151 | 16-Oct-18 15:16:00 | 16-Oct-18 15:16:00 | 16-Oct-18 15:27:09 |
| PM/Scl 100 Antibody, IgG | Negative | | [Negative] | 18-289-900151 | 16-Oct-18 15:16:00 | 16-Oct-18 15:16:00 | 16-Oct-18 15:27:09 |
| Fibrillarin (U3 RNP) Ab, IgG | Negative | | [Negative] | 18-289-900151 | 16-Oct-18 15:16:00 | 16-Oct-18 15:16:00 | 16-Oct-18 15:27:09 |
| SSB (La) (ENA) Antibody, IgG | 30 | AU/mL | [0-40] | 18-289-900151 | 16-Oct-18 15:16:00 | 16-Oct-18 15:16:00 | 16-Oct-18 15:27:09 |
| Scleroderma (Scl-70) (ENA) Antibody, IgG | 0 | AU/mL | [0-40] | 18-289-900151 | 16-Oct-18 15:16:00 | 16-Oct-18 15:16:00 | 16-Oct-18 15:27:09 |
| RNA Polymerase III Antibody, IgG | 1 | Units | [0-19] | 18-289-900151 | 16-Oct-18 15:16:00 | 16-Oct-18 15:16:00 | 16-Oct-18 15:27:09 |
| Chromatin Antibody, IgG | 5 | Units | [0-19] | 18-289-900151 | 16-Oct-18 15:16:00 | 16-Oct-18 15:16:00 | 16-Oct-18 15:27:09 |
| Antinuclear Antibody (ANA), HEp-2, IgG | Detected * | | [<1:80] | 18-289-900151 | 16-Oct-18 15:16:00 | 16-Oct-18 15:16:00 | 16-Oct-18 15:20:01 |
| ANA Pattern | Homogenous | | | 18-289-900151 | 16-Oct-18 15:16:00 | 16-Oct-18 15:16:00 | 16-Oct-18 15:20:11 |
| ANA Titer | 1:320 * | | | 18-289-900151 | 16-Oct-18 15:16:00 | 16-Oct-18 15:16:00 | 16-Oct-18 15:20:09 |
| ANA Pattern 2 | Nucleolar * | | | 18-289-900151 | 16-Oct-18 15:16:00 | 16-Oct-18 15:16:00 | 16-Oct-18 15:20:16 |
| ANA Titer 2 | 1:160 * | | | 18-289-900151 | 16-Oct-18 15:16:00 | 16-Oct-18 15:16:00 | 16-Oct-18 15:20:15 |
| Cytoplasmic Pattern Titer | 1:80 * | | | 18-289-900151 | 16-Oct-18 15:16:00 | 16-Oct-18 15:16:00 | 16-Oct-18 15:20:13 |
| ANA Interpretive Comment | See Note | | | 18-289-900151 | 16-Oct-18 15:16:00 | 16-Oct-18 15:16:00 | 16-Oct-18 15:20:01 |

16-Oct-18 15:16:00 ANA Interpretive Comment

Homogeneous Pattern

Clinical associations: SLE, drug-induced SLE or JIA.

Main autoantibodies: Anti-dsDNA, anti-histones or anti-chromatin (anti-nucleosome)

Nucleolar Pattern

Clinical associations: SSc, SSc/PM overlap, SjS

Main autoantibodies: Anti-PM/Scl, anti-RNA polymerase, anti-URNP, anti-U3-RNP (anti-fibrillarin), anti-Th/To, NOR-90

Cytoplasmic Pattern

Clinical associations: ARS, ILD, IM, SLE, SSc, SjS, RA, MCTD, PBC, AIH, infectious, neurologic, and other inflammatory conditions. May also be found in healthy individuals

Main autoantibodies: Anti-Ribosomal P, anti-tRNA synthetase (anti-Jo-1, anti-PL-7, anti-PL-12, anti-EJ, anti-OJ), anti-signal recognition particle (anti-SRP) or anti-mitochondria (anti-AMA)

Clinical Relevance

Antisynthetase syndrome (ARS), chronic active hepatitis (CAH), inflammatory myopathies (IM) [dermatomyositis (DM), polymyositis (PM), necrotizing autoimmune myopathy (NAM)], interstitial lung disease (ILD), juvenile idiopathic arthritis (JIA), mixed connective tissue disease (MCTD), primary biliary cholangitis (PBC), rheumatoid arthritis (RA), systemic autoimmune rheumatic diseases (SARD), Sjogren syndrome (SjS), systemic lupus erythematosus (SLE), systemic sclerosis (SSc), undifferentiated connective tissue disease (UCTD).

16-Oct-18 15:16:00 Double-Stranded DNA (dsDNA) Ab IgG ELISA:

INTERPRETIVE INFORMATION: Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA

Positivity for anti-double stranded DNA (anti-dsDNA) IgG antibody is a diagnostic criterion of systemic lupus erythematosus (SLE). Specimens are initially screened by enzyme-linked immunosorbent assay (ELISA). All ELISA results reported as "detected"

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(positive) are confirmed by a highly specific IFA titer (Crithidia luciliae indirect fluorescent test [CLIFT]). Some patients with early or inactive SLE may be positive for anti-dsDNA IgG by ELISA but negative by CLIFT. If the patient is negative by CLIFT but positive by ELISA and clinical suspicion remains, consider antinuclear antibody (ANA) testing by IFA. Additional information and recommendations for testing may be found at <http://www.arupconsult.com/Topics/AutoimmuneDz/ConnectiveTissueDz/index.html>.

16-Oct-18 15:16:00 Double-Stranded DNA (dsDNA) Ab IgG IFA:
INTERPRETIVE INFORMATION: Double-Stranded DNA (dsDNA) Antibody, IgG by IFA (using Crithidia luciliae)

Positivity for anti-double stranded DNA (anti-dsDNA) IgG antibody is a diagnostic criterion of systemic lupus erythematosus (SLE). The presence of the anti-dsDNA IgG antibody is identified by IFA titer (*Crithidia luciliae* indirect fluorescent test [CLIFT]). CLIFT is highly specific for SLE with a sensitivity of 50-60 percent.

Some patients with early or inactive SLE may be positive for anti-dsDNA IgG by ELISA but negative by CLIFT. If the CLIFT result is negative but the patient has a positive ELISA and clinical suspicion remains, consider antinuclear antibody (ANA) testing by IFA. Additional information and recommendations for testing may be found at <http://www.arupconsult.com/Topics/AutoimmuneDz/ConnectiveTissueDz/index.html>.

16-Oct-18 15:16:00 Smith (ENA) Antibody, IgG:
INTERPRETIVE INFORMATION: SMITH (ENA) Ab, IgG

29 AU/mL or Less Negative
30 - 40 AU/mL Equivocal
41 AU/mL or Greater Positive

Smith antibody is very specific for systemic lupus erythematosus (SLE) but only occurs in 30-35% of SLE cases. The presence of antibodies to Smith is often associated with renal disease.

16-Oct-18 15:16:00 SSA-52 (Ro52) (ENA) Antibody, IgG:
INTERPRETIVE INFORMATION: SSA-52 (Ro52) (ENA) Antibody, IgG

29 AU/mL or Less Negative
30 - 40 AU/mL Equivocal
41 AU/mL or Greater Positive

SSA-52 (Ro52) and/or SSA-60 (Ro60) antibodies are associated with a diagnosis of Sjogren syndrome, systemic lupus erythematosus (SLE), and systemic sclerosis. SSA-52 antibody overlaps significantly with the major SSc-related antibodies. SSA-52 (Ro52) antibody occurs frequently in patients with inflammatory myopathies, often in the presence of interstitial lung disease.

16-Oct-18 15:16:00 SSA-60 (Ro60) (ENA) Antibody, IgG:
REFERENCE INTERVAL: SSA-60 (Ro60) (ENA) Antibody, IgG

29 AU/mL or Less Negative

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30 - 40 AU/mL Equivocal
41 AU/mL or Greater Positive

16-Oct-18 15:16:00 Ribonucleic Protein (U1) (ENA) Ab, IgG:
INTERPRETIVE INFORMATION: Ribonucleic Protein (ENA)Antibody, IgG

29 AU/mL or Less Negative
30 - 40 AU/mL Equivocal
41 AU/mL or Greater Positive

RNP antibody is seen in 95-100 percent of mixed connective tissue disease and is considered specific for this syndrome if other antibodies are negative; RNP is also present in 20-30 percent of systemic lupus erythematosus and 15-25 percent of progressive systemic sclerosis. RNP antigens also contain epitopes that are immunologically identical to free Smith antigens, therefore, the Smith antibody response must be considered when interpreting RNP results.

16-Oct-18 15:16:00 PM/Scl 100 Antibody, IgG:
INTERPRETIVE INFORMATION: PM/Scl-100 Antibody, IgG by
Immunoblot

The presence of PM/Scl-100 IgG antibody along with a positive ANA IFA nucleolar pattern is associated with connective tissue diseases such as polymyositis (PM), dermatomyositis (DM), systemic sclerosis (SSc), and polymyositis/systemic sclerosis overlap syndrome. The clinical relevance of PM/Scl-100 IgG antibody with a negative ANA IFA nucleolar pattern is unknown. PM/Scl-100 is the main target epitope of the PM/Scl complex, although antibodies to other targets not detected by this assay may occur.

Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement D: aruplab.com/CS

16-Oct-18 15:16:00 Fibrillarin (U3 RNP) Ab, IgG:
Interpretive Information: Fibrillarin (U3 RNP) Antibody, IgG

The presence of fibrillarin (U3-RNP) IgG antibodies in association with an ANA IFA nucleolar pattern is suggestive of systemic sclerosis (SSc). In SSc, these antibodies are associated with distinct clinical features, such as younger age at disease onset, frequent internal organ involvement (pulmonary hypertension, myositis and renal disease). Fibrillarin antibodies are detected more frequently in African American patients with SSc compared to other ethnic groups. Strong correlation with ANA IFA results is recommended.

In a multi-ethnic cohort of SSc patients (n=98), U3-RNP antibodies detected by immunoblot had an agreement of 98.9 percent with the gold standard immunoprecipitation (IP) assay. Approximately 71 percent (5/7) of the borderline U3-RNP results with ANA nucleolar pattern in this cohort were IP negative.

Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement D: aruplab.com/CS

16-Oct-18 15:16:00 SSB (La) (ENA) Antibody, IgG:
INTERPRETIVE INFORMATION: SSB (La) (ENA) Ab, IgG

29 AU/mL or Less Negative

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30 - 40 AU/mL Equivocal
41 AU/mL or Greater Positive

SSB (La) antibody is seen in 50-60% of Sjogren syndrome cases and is specific if it is the only ENA antibody present. 15-25% of patients with systemic lupus erythematosus (SLE) and 5-10% of patients with progressive systemic sclerosis (PSS) also have this antibody.

16-Oct-18 15:16:00 Scleroderma (Scl-70) (ENA) Antibody, IgG:
INTERPRETIVE INFORMATION: Scleroderma (Scl-70) (ENA) Ab, IgG

29 AU/mL or Less Negative
30 - 40 AU/mL Equivocal
41 AU/mL or Greater Positive

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.

16-Oct-18 15:16:00 RNA Polymerase III Antibody, IgG:
INTERPRETIVE INFORMATION: RNA Polymerase III Antibody, IgG

19 Units or lessNegative
20 - 39 UnitsWeak Positive
40 - 80 UnitsModerate Positive
81 Units or greater ...Strong Positive

The presence of RNA polymerase III IgG antibodies is considered diagnostic of systemic sclerosis (SSc). RNA polymerase III IgG antibodies occur in about 11-23 percent of SSc patients, and typically in the absence of anti-centromere and anti-Scl-70 antibodies. The presence of RNA polymerase III IgG antibodies may be predictive of an increased risk of skin involvement and hypertensive renal failure associated with the diffuse cutaneous form of SSc.

A negative result indicates no detectable IgG antibodies to the dominant antigen of RNA polymerase III and does not rule out the possibility of SSc. False-positive results may also occur due to non-specific binding of immune complexes. Strong clinical correlation is recommended.

If clinical suspicion remains, consider additional testing for other antibodies associated with SSc, including centromere, Scl-70, U3-RNP, PM/Scl, or Th/To.

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16-Oct-18 15:16:00 Chromatin Antibody, IgG:
INTERPRETIVE INFORMATION: Chromatin Antibody, IgG

19 Units or less: Negative
20 - 60 Units: Moderate Positive
61 Units or greater: Strong Positive

The presence of anti-chromatin antibodies may be useful in the diagnosis of systemic lupus erythematosus (SLE) or drug-induced lupus (DIL) and have been reported to be predictive of lupus nephritis, especially when antibody levels are high.

16-Oct-18 15:16:00 ANA Interpretive Comment:
INTERPRETIVE INFORMATION: ANA Interpretive Comment

Presence of antinuclear antibodies (ANA) is a hallmark feature of systemic autoimmune rheumatic diseases (SARD). ANA lacks diagnostic specificity and is associated with a variety of diseases (cancers, autoimmune, infectious, and inflammatory conditions) and may also occur in healthy individuals in varying prevalence. The lack of diagnostic specificity requires confirmation of positive ANA by more-specific serologic tests. ANA (nuclear reactivity) positive patterns reported include centromere, homogeneous, nuclear dots, nucleolar, or speckled. Cytoplasmic pattern is reported as ANA negative. All patterns are reported to endpoint titers (1:2560). Reported patterns may help guide differential diagnosis, although they may not be specific for individual antibodies or diseases. Negative results do not necessarily rule out SARD.