Antinuclear Antibodies (ANA), IgG by ELISA with Reflex to ANA HEp-2 Substrate, IgG by IFA and ENA Confirmation
ARUP test code 0050317

**Anti-Nuclear Ab (ANA), IgG by ELISA**

**Detected** * (Ref Interval: None Detected)

Antibodies to Anti-Nuclear Antibodies (ANA) detected. Additional testing to follow.

**INTERPRETIVE INFORMATION:** Anti-Nuclear Antibodies (ANA), IgG by ELISA

Antinuclear Antibodies (ANA), IgG by ELISA: ANA specimens are screened using enzyme-linked immunosorbent assay (ELISA) methodology. All ELISA results reported as Detected are further tested by indirect fluorescent assay (IFA) using HEp-2 substrate with an IgG-specific conjugate. The ANA ELISA screen is designed to detect antibodies against dsDNA, histones, SS-A (Ro), SS-B (La), Smith, Smith/RNP, Scl-70, Jo-1, centromeric proteins, other antigens extracted from the HEp-2 cell nucleus. ANA ELISA assays have been reported to have lower sensitivities than ANA IFA for systemic autoimmune rheumatic diseases (SARD).

Negative results do not necessarily rule out SARD.

Double-Stranded DNA (dsDNA) Antibody, IgG by ELISA with Reflex to dsDNA Antibody, IgG by IFA
ARUP test code 0050215

**Double-Stranded DNA (dsDNA) Ab IgG ELISA**

**Detected** * (Ref Interval: None Detected)

**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" (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.
Double-Stranded DNA (dsDNA) Antibody, IgG by IFA (using Crithidia luciliae)

ARUP test code 2002693

Double-Stranded DNA (dsDNA) Ab IgG IFA 1:320 * (Ref Interval: 0:1:10)

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.

Smith (ENA) Antibody, IgG

ARUP test code 0050085

Smith (ENA) Antibody, IgG 65 AU/mL H (Ref Interval: 0-40)

INTERPRETIVE INFORMATION: Smith (ENA) Antibody, IgG

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

Smith antibody is highly specific (greater than 90 percent) for systemic lupus erythematosus (SLE) but only occurs in 30-35 percent of SLE cases. The presence of antibodies to Smith has variable associations with SLE clinical manifestations.

SSA 52 and 60 (Ro) (ENA) Antibodies, IgG

ARUP test code 2012074

SSA-52 (Ro52) (ENA) Antibody, IgG 65 AU/mL H (Ref Interval: 0-40)

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.

SSA-60 (Ro60) (ENA) Antibody, IgG 65 AU/mL H (Ref Interval: 0-40)

H=High, L=Low, *=Abnormal, C=Critical
REFERENCE INTERVAL: SSA-60 (Ro60) (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
ARUP test code 0050470
Smith/RNP (ENA) Ab, IgG 0

Jo-1 Antibody, IgG
ARUP test code 0099592
Jo-1 (Histidyl-tRNA Synthetase) Ab, IgG 65 AU/mL H (Ref Interval: 0-40)
INTERPRETIVE INFORMATION: Jo-1 Antibody, IgG

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

Presence of Jo-1 (antihistidyl transfer RNA [t-RNA] synthetase) antibody is associated with polymyositis and may also be seen in patients with dermatomyositis. Jo-1 antibody is associated with pulmonary involvement (interstitial lung disease), Raynaud phenomenon, arthritis, and mechanic's hands (implicated in antisynthetase syndrome).

SSB (La) (ENA) Antibody, IgG
ARUP test code 0090692
SSB (La) (ENA) Antibody, IgG 65 AU/mL H (Ref Interval: 0-40)
INTERPRETIVE INFORMATION: SSB (La) (ENA) Ab, IgG

29 AU/mL or Less .............. Negative
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.

Scleroderma (Scl-70) (ENA) Antibody, IgG
ARUP test code 0050599
Scleroderma (Scl-70) (ENA) Antibody, IgG 56 AU/mL H (Ref Interval: 0-40)
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-1 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.

Antinuclear Antibody (ANA) with HEp-2 Substrate, IgG by IFA

ARUP test code 3000082

Antinuclear Antibody (ANA), HEp-2, IgG

Detected * (Ref Interval: <1:80)

ANA Interpretive Comment

See Note

Homogeneous Pattern
Clinical associations: SLE, drug-induced SLE or JIA.
Main autoantibodies: Anti-dsDNA, anti-histones or anti-chromatin (anti-nucleosome)

List of Abbreviations
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).
INTERPRETIVE INFORMATION: ANA Interpretive Comment

Presence of antinuclear antibodies (ANA) is a hallmark feature of systemic autoimmune rheumatic diseases (SARD). However, 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. ANA (cytoplasmic reactivity) positive patterns reported include reticular/AMA, discrete/GW body-like, polar/golgi-like, cytoplasmic speckled or rods and rings. All positive 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. Mitotic staining patterns not reported. Negative results do not necessarily rule out SARD.

Antinuclear Antibody (ANA) with HEp-2 Substrate, IgG by IFA, Single Pattern (Reflex for 3000082 ANA IFA AB Only Not Orderable by Clients)

ARUP test code 3000083

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Extractable Nuclear Antigen Antibodies (RNP, Smith, SSA 52, SSA 60, Scleroderma, Jo-1, and SSB), and Double Stranded DNA (dsDNA) Antibody IgG to follow.

H=High, L=Low, *=Abnormal, C=Critical

Patient: Patient, Example
ARUP Accession: 21-110-11532
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
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