

Client: Example Client ABC123
123 Test Drive
Salt Lake City, UT 84108
UNITED STATES

Physician: Doctor, Example

Patient: Patient, Example

DOB: Unknown
Gender: Unknown
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
Collection Date: 00/00/0000 00:00

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>.

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

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: <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

Unless otherwise indicated, testing performed at:

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 0050692

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)**

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

Unless otherwise indicated, testing performed at:

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.

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).

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Unless otherwise indicated, testing performed at:

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

ANA Pattern	Homogeneous	*
ANA Titer	1:1280	*
<p>Extractable Nuclear Antigen Antibodies (RNP, Smith, SSA 52, SSA 60, Scleroderma, Jo-1, and SSB), and Double Stranded DNA (dsDNA) Antibody IgG to follow.</p>		

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Unless otherwise indicated, testing performed at:

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
Anti-Nuclear Ab (ANA), IgG by ELISA	21-110-115332	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Double-Stranded DNA (dsDNA) Ab IgG ELISA	21-110-115332	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Double-Stranded DNA (dsDNA) Ab IgG IFA	21-110-115332	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Smith (ENA) Antibody, IgG	21-110-115332	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
SSA-52 (Ro52) (ENA) Antibody, IgG	21-110-115332	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
SSA-60 (Ro60) (ENA) Antibody, IgG	21-110-115332	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Smith/RNP (ENA) Ab, IgG	21-110-115332	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Jo-1 (Histidyl-tRNA Synthetase) Ab, IgG	21-110-115332	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
SSB (La) (ENA) Antibody, IgG	21-110-115332	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Scleroderma (Scl-70) (ENA) Antibody, IgG	21-110-115332	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Antinuclear Antibody (ANA), HEp-2, IgG	21-110-115332	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
ANA Pattern	21-110-115332	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
ANA Titer	21-110-115332	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
ANA Interpretive Comment	21-110-115332	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00

END OF CHART

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

Unless otherwise indicated, testing performed at:

ARUP LABORATORIES | 800-522-2787 | aruplab.com
500 Chipeta Way, Salt Lake City, UT 84108-1221
Tracy I. George, MD, Laboratory Director

Patient: Patient, Example
ARUP Accession: 21-110-115332
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
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