

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 **55 IU H**

(Ref Interval: 0-24)

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 Jonathan R. Genzen, MD, PhD, Laboratory Director Patient: Patient, Example ARUP Accession: 23-101-102428 Patient Identifiers: 01234567890ABCD, 012345 Visit Number (FIN): 01234567890ABCD Page 1 of 6 | Printed: 4/12/2023 11:31:52 AM 4848



INTERPRETIVE INFORMATION: Double-Stranded DNA (dsDNA) Ab IgG ELISA 24 IU or less.....Negative 25-30 IU.....Borderline Positive 30-60 IU.....Low Positive 60-200 IU.....Positive 201 IU or greater...Strong Positive

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). If ordered as reflex (0050215), positive ELISA results (>24 IU) will be reflexed to a highly specific IFA titer (Crithidia luciliae indirect fluorescent test [CLIFT]) for confirmation. 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 https://arupconsult.com/content/systemic-lupus-erythematosus.

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

ARUP test code 2002693

| Double-Stranded DNA (dsDNA) Ab IgG IFA | INTERPRETIVE 1 | * (Ref Interval: <1:10) INFORMATION: Double-Stranded DNA (dsDNA) Antibody, sing Crithidia luciliae) |
|----------------------------------------|----------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | antibody is a erythematosus is identified fluorescent te | r anti-double stranded DNA (anti-dsDNA) IgG diagnostic criterion of systemic lupus (SLE). The presence of the anti-dsDNA IgG antibody by IFA titer (Crithidia luciliae indirect est [CLIFT]). CLIFT is highly specific for SLE with of 50-60 percent. |
| | anti-dsDNA Igo result is nega clinical suspi testing by IFA testing may be | with early or inactive SLE may be positive for G by ELISA but negative by CLIFT. If the CLIFT ative but the patient has a positive ELISA and icion remains, consider antinuclear antibody (ANA) A. Additional information and recommendations for a found at upconsult.com/Topics/AutoimmuneDz/ConnectiveTissueDz |

Smith (ENA) Antibody, IgG

ARUP test code 0050085

Smith (ENA) Antibody, IgG

85 AU/mL

(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 |

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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.

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

| SSA-52 (Ro52) (ENA) Antibody, IgG | 456 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 interstitia lung disease. | | |
| SSA-60 (Ro60) (ENA) Antibody, IgG | 88 AU/mL H (Ref Interval: 0-40) | | |
| | 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 | | |

ARUP test code 0050470

| Smith/RNP (ENA) Ab, IgG | 35 Units H (Ref Interval: 0-19) INTERPRETIVE INFORMATION: Smith/RNP (ENA) Antibody, IgG |
|-------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | 19 Units or Less Negative 20 to 39 Units Weak Positive 40 to 80 Units Moderate Positive 81 Units or greater Strong Positive |
| | Smith/RNP antibodies are frequently seen in patients with mixed connective tissue disease (MCTD) and are also associated with other systemic autoimmune rheumatic diseases (SARDs) such as systemic lupus erythematosus (SLE), systemic sclerosis, and myositis. Antibodies targeting the Smith/RNP antigenic complex also recognize Smith antigens, therefore, the Smith antibody response must be considered when interpreting these results. |

Jo-1 Antibody, IgG

ARUP test code 0099592

| Jo-1 (Histidyl-tRNA Synthetase) Ab, IgG | |
|-----------------------------------------|--|
|-----------------------------------------|--|

55 AU/mL

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(Ref Interval: 0-40)

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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

655 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 | 65 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-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

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* 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 contromere homogeneous puclear data rusclear or cosciled 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)

| ANA Pattern | Homogeneous * |
|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| ANA Titer | 1:640 * |
| | Extractable Nuclear Antigen Antibodies (RNP, Smith, SSA 52, SSA 60, Scleroderma, Jo-1, and SSB), and Double Stranded DNA (dsDNA) Antibody IgG to follow. |

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| VERIFIED/REPORTED DATES | | | | |
|------------------------------------------|---------------|------------------|------------------|-------------------|
| Procedure | Accession | Collected | Received | Verified/Reported |
| Anti-Nuclear Ab (ANA), IgG by ELISA | 23-101-102428 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| Double-Stranded DNA (dsDNA) Ab IgG ELISA | 23-101-102428 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| Double-Stranded DNA (dsDNA) Ab IgG IFA | 23-101-102428 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| Smith (ENA) Antibody, IgG | 23-101-102428 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| SSA-52 (Ro52) (ENA) Antibody, IgG | 23-101-102428 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| SSA-60 (Ro60) (ENA) Antibody, IgG | 23-101-102428 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| Smith/RNP (ENA) Ab, IgG | 23-101-102428 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| Jo-1 (Histidyl-tRNA Synthetase) Ab, IgG | 23-101-102428 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| SSB (La) (ENA) Antibody, IgG | 23-101-102428 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| Scleroderma (Scl-70) (ENA) Antibody, IgG | 23-101-102428 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| Antinuclear Antibody (ANA), HEp-2, IgG | 23-101-102428 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| ANA Pattern | 23-101-102428 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| ANA Titer | 23-101-102428 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |
| ANA Interpretive Comment | 23-101-102428 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00 |

END OF CHART

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