ARUP LABORATORIES | aruplab.com
500 Chipeta Way, Salt Lake City, Utah 84108-1221
phone: 801-583-2787, toll free: 800-522-2787
Tracy I. George, MD, Chief Medical Officer

Patient Report

Patient Age/Sex: Unknown

Specimen Collected: 14-Dec-21 07:52

Lupus Profile with Reflex |**Received: 14-Dec-21 07:52** **Report/Verified: 14-Dec-21 08:30**

Procedure	Result	Units	Reference Interval
Thyroid Peroxidase (TPO) Antibody	**25.0** H	IU/mL	0.0-9.0
Complement Component 3	900 i1	mg/dL	
Complement Component 4	2000 i2	mg/dL	
Anti-Nuclear Ab (ANA), IgG by ELISA	**Detected** * f1 i3		None Detected
Double-Stranded DNA (dsDNA) Ab IgG ELISA	**65** H i4	IU	0-24
Smith (ENA) Antibody, IgG	**244** H i5	AU/mL	0-40
Centromere Ab,IgG	**569** H i6	AU/mL	0-40
SSA-52 (Ro52) (ENA) Antibody,IgG	**100** H i7	AU/mL	0-40
SSA-60 (Ro60) (ENA) Antibody,IgG	**150** H i8	AU/mL	0-40
Smith/RNP (ENA) Ab,IgG	**50** H i9	Units	0-19
SSB (La) (ENA) Antibody,IgG	**188** H i10	AU/mL	0-40
Scleroderma (Scl-70) (ENA) Antibody,IgG	**166** H i11	AU/mL	0-40
Cardiolipin Antibody IgG	**65** H i12	GPL	<=14
Cardiolipin Antibody IgM	**52** H i13	MPL	<=12
Cardiolipin Antibody IgA	**53** H i14	APL	<=11

Antinuclear Antibody (ANA), HEp-2, IgG |**Received: 14-Dec-21 07:52** **Report/Verified: 14-Dec-21 08:31**

Procedure	Result	Units	Reference Interval
Antinuclear Antibody (ANA),HEp-2,IgG	**Detected** *		<1:80
ANA Interpretive Comment	See Note t1 i15		

dsDNA (Crithidia luciliae) Ab IgG by IFA |**Received: 14-Dec-21 07:52** **Report/Verified: 14-Dec-21 08:31**

Procedure	Result	Units	Reference Interval
Double-Stranded DNA (dsDNA) Ab IgG IFA	**1:160** * i16		<1:10

Antinuclear Ab, Single Pattern |**Received: 14-Dec-21 07:52** **Report/Verified: 14-Dec-21 08:32**

Procedure	Result	Units	Reference Interval
ANA Titer	**1:1280** *		
ANA Pattern	**Nuclear Dot** *		

*=Abnormal, #=Corrected, C=Critical, f=Result Footnote, H-High, i-Test Information, L-Low, t-Interpretive Text, @=Performing lab

Interpretive Text

t1: 14-Dec-21 07:52 (ANA Interpretive Comment)

Nuclear Dots Pattern
Clinical associations: PBC, DM, SjS, SLE, SSc, PM
Main autoantibodies: Anti-NXP-2, anti-Sp100

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).

Result Footnote

f1: Anti-Nuclear Ab (ANA), IgG by ELISA

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

Test Information

i1: Complement Component 3

REFERENCE INTERVAL: Complement Component 3

Access complete set of age- and/or gender-specific reference intervals for this test in the ARUP Laboratory Test Directory (aruplab.com).

i2: Complement Component 4

REFERENCE INTERVAL: Complement Component 4

Access complete set of age- and/or gender-specific reference intervals for this test in the ARUP Laboratory Test Directory (aruplab.com).

i3: Anti-Nuclear Ab (ANA), IgG by ELISA

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.

i4: Double-Stranded DNA (dsDNA) Ab IgG ELISA

INTERPRETIVE INFORMATION: Double-Stranded DNA (dsDNA) Ab IgG ELISA
24 IU or less.....Negative

Test Information

i4: Double-Stranded DNA (dsDNA) Ab IgG ELISA

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.

i5: Smith (ENA) Antibody, IgG

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.

i6: Centromere Ab, IgG

INTERPRETIVE INFORMATION: Centromere Ab, IgG

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

When detected by this multiplex bead assay, the presence of centromere antibodies is mainly associated with CREST syndrome, a variant of systemic sclerosis (SSc). These antibodies target the centromere B, a dominant antigen of the centromeric complex associated with the centromere pattern observed in antinuclear antibody (ANA) testing by IFA. Centromere antibodies may also be seen in a varying percentage of patients with other autoimmune diseases, including diffuse cutaneous SSc, Raynaud syndrome, interstitial pulmonary fibrosis, autoimmune liver disease, systemic lupus erythematosus (SLE) and rheumatoid arthritis (RA).

A negative result indicates no detectable IgG antibodies to centromere B. If the result is negative but clinical suspicion for SSc is strong, consider testing for

Test Information

i6: Centromere Ab, IgG

ANA by IFA along with other antibodies associated with SSc, including Scl-70, U3-RNP, PM/Scl, or Th/To.

i7: 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.

i8: SSA-60 (Ro60) (ENA) Antibody, IgG

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

i9: Smith/RNP (ENA) Ab, IgG

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.

i10: SSB (La) (ENA) Antibody, IgG

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

Test Information

i10: SSB (La) (ENA) Antibody, IgG

erythematosus (SLE) and 5-10% of patients with progressive systemic sclerosis (PSS) also have this antibody.

i11: 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.

i12: Cardiolipin Antibody IgG

INTERPRETIVE INFORMATION: Anti-Cardiolipin IgG Ab

<=14 GPL: Negative
15-19 GPL: Indeterminate
20-80 GPL: Low to Moderately Positive
81 GPL or above: High Positive

The persistent presence of IgG and/or IgM cardiolipin (CL) antibodies in moderate or high levels (greater than 40 GPL and/or greater than 40 MPL units) is a laboratory criterion for the diagnosis of antiphospholipid syndrome (APS). Persistence is defined as moderate or high levels of IgG and/or IgM CL antibodies detected in two or more specimens drawn at least 12 weeks apart (J Throm Haemost. 2006;4:295-306). Lower positive levels of IgG and/or IgM CL antibodies (above cutoff but less than 40 GPL and/or less than 40 MPL units) may occur in patients with the clinical symptoms of APS; therefore, the actual significance of these levels is undefined. Results should not be used alone for diagnosis and must be interpreted in light of APS-specific clinical manifestations and/or other criteria phospholipid antibody tests.

Test Information

i13: Cardiolipin Antibody IgM

INTERPRETIVE INFORMATION: Anti-Cardiolipin IgM

<=12 MPL: Negative
13-19 MPL: Indeterminate
20-80 MPL: Low to Moderately Positive
81 MPL or above: High Positive

The persistent presence of IgG and/or IgM cardiolipin (CL) antibodies in moderate or high levels (greater than 40 GPL and/or greater than 40 MPL units) is a laboratory criterion for the diagnosis of antiphospholipid syndrome (APS). Persistence is defined as moderate or high levels of IgG and/or IgM CL antibodies detected in two or more specimens drawn at least 12 weeks apart (J Throm Haemost. 2006;4:295-306). Lower positive levels of IgG and/or IgM CL antibodies (above cutoff but less than 40 GPL and/or less than 40 MPL units) may occur in patients with the clinical symptoms of APS; therefore, the actual significance of these levels is undefined. Results should not be used alone for diagnosis and must be interpreted in light of APS-specific clinical manifestations and/or other criteria phospholipid antibody tests.

i14: Cardiolipin Antibody IgA

INTERPRETIVE INFORMATION: Cardiolipin Antibodies, IgA

<=11 APL: Negative
12-19 APL: Indeterminate
20-80 APL: Low to Moderately Positive
81 APL or above: High Positive

i15: ANA Interpretive Comment

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.

i16: Double-Stranded DNA (dsDNA) Ab IgG IFA

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

Test Information

i16: Double-Stranded DNA (dsDNA) Ab IgG IFA

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.