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*****Example Report*****

Patient Age/Gender: Unknown Unknown
Printed: 17-Jun-19 09:46:07

Procedure	Result		Units	Ref Interval	Accession	Collected	Received	Reported/ Verified
Smith/RNP (ENA) Ab, IgG	0		AU/mL	[0-40]	19-161-900124	10-Jun-19 11:53:00	10-Jun-19 11:53:00	10-Jun-19 12:03:34
PM/Scl 100 Antibody, IgG	Negative			[Negative]	19-161-900124	10-Jun-19 11:53:00	10-Jun-19 11:53:00	10-Jun-19 12:03:34
Fibrillarin (U3 RNP) Ab, IgG	**Positive**	*		[Negative]	19-161-900124	10-Jun-19 11:53:00	10-Jun-19 11:53:00	10-Jun-19 12:03:34
Scleroderma (Scl-70) (ENA) Antibody, IgG	2		AU/mL	[0-40]	19-161-900124	10-Jun-19 11:53:00	10-Jun-19 11:53:00	10-Jun-19 12:03:34
RNA Polymerase III Antibody, IgG	5		Units	[0-19]	19-161-900124	10-Jun-19 11:53:00	10-Jun-19 11:53:00	10-Jun-19 12:03:34
Antinuclear Antibody (ANA), HEp-2, IgG	**Detected**	*		[<1:80]	19-161-900124	10-Jun-19 11:53:00	10-Jun-19 11:53:00	10-Jun-19 12:03:34
ANA Pattern	**Speckled**	*			19-161-900124	10-Jun-19 11:53:00	10-Jun-19 11:53:00	10-Jun-19 12:03:42
ANA Titer	**1:320**	*			19-161-900124	10-Jun-19 11:53:00	10-Jun-19 11:53:00	10-Jun-19 12:03:41
ANA Interpretive Comment	See Note				19-161-900124	10-Jun-19 11:53:00	10-Jun-19 11:53:00	10-Jun-19 12:03:34

10-Jun-19 11:53:00 ANA Interpretive Comment
Speckled Pattern
Clinical associations: SLE, SSc, SjS, DM, PM, MCTD, UCTD. May also be found in healthy individuals
Main autoantibodies: Anti-SSA-52 (Ro52), anti-SSA-60 (Ro60), anti-SS-B/LA, anti-Topo-1 (anti-Scl-70), Smith, anti-U1-RNP, anti-U2-RNP, anti-Mi-2, anti-TIF1g, anti-Ku, anti-RNA polymerase, anti-DFS70/LEDGF-P75

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).

10-Jun-19 11:53:00 Smith/RNP (ENA) Ab, IgG:
INTERPRETIVE INFORMATION: Smith/RNP (ENA) Antibody, IgG

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

10-Jun-19 11:53:00 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

10-Jun-19 11:53:00 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

10-Jun-19 11:53:00 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.

10-Jun-19 11:53:00 RNA Polymerase III Antibody, IgG:
INTERPRETIVE INFORMATION: RNA Polymerase III Antibody, IgG

19 Units or less .....Negative
20 - 39 Units .....Weak Positive
40 - 80 Units .....Moderate Positive
81 Units or greater ...Strong Positive

The presence of RNA polymerase III IgG antibody, when considered in conjunction with other laboratory and clinical findings, is an aid in the diagnosis of systemic sclerosis (SSc) with increased incidence of skin involvement and renal crisis with the diffuse

cutaneous form of SSc. RNA polymerase III IgG antibody occur in about 11-23 percent of SSc patients, and typically in the absence of anti-centromere and anti-Scl-70 antibodies.

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.

10-Jun-19 11:53:00 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.