



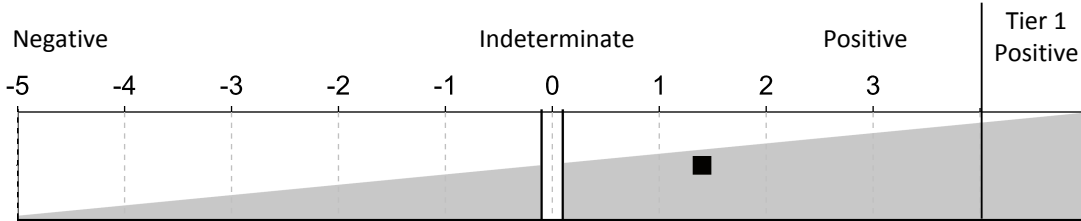
Order ID 739813
 Provider Exagen Provider MD

Specimen
 Collected 01/19/2023
 Received 01/20/2023
Test Order
 Created 01/20/2023
 Reported 01/25/2023

Patient
Sample, Susan S.
 Gender - DOB Female - 01/01/1996
 Identifier Received
 Exagen ID 541163

AVISE CTD Test Report

AVISE Lupus Result: **Positive - Index: 1.4**



Tier 1 Analytes	Value	Interpretation	Reference Range	Tier 1 Assessment
Anti-dsDNA IgG	20.00 IU/mL	Negative	<201 - Negative 201-<302 - Equivocal ≥302 - Positive	Negative
Confirmation by Crithidia luciliae		N/A		
Anti-Smith IgG	1.0 U/mL	Negative	<7 - Negative 7-10 - Equivocal >10 - Positive	
CB-CAP: EC4d - Erythrocyte-bound C4d	25 Net MFI	POSITIVE	<15 - Negative 15 -75 - Positive >75 - Strong Positive	
CB-CAP: BC4d - B-lymphocyte-bound C4d	100 Net MFI	POSITIVE	<61 - Negative 61-200 - Positive >200 - Strong Positive	
Note: Criteria for Tier 1 Positive not met.				

Tier 2 Analytes	Value	Interpretation	Reference Range	Tier 2 Assessment
ANA IgG	40.00 Units	POSITIVE	<20 - Negative 20-<60 - Positive ≥60 - Strong Positive	Positive
CB-CAP: EC4d - Erythrocyte-bound C4d	25 Net MFI	POSITIVE	<15 - Negative 15-75 - Positive >75 - Strong Positive	
CB-CAP: BC4d - B-lymphocyte-bound C4d	100 Net MFI	POSITIVE	<61 - Negative 61-200 - Positive >200 - Strong Positive	
Anti-SS-B/La IgG	1.0 U/mL	Negative	<7 - Negative 7-10 - Equivocal >10 - Positive	
Anti-Scl-70 IgG	1.0 U/mL	Negative	<7 - Negative 7-10 - Equivocal >10 - Positive	
Anti-Centromere Protein B (CENP) IgG	1.0 U/mL	Negative	<7 - Negative 7-10 - Equivocal >10 - Positive	
Anti-Jo-1 IgG	1.0 U/mL	Negative	<7 - Negative 7-10 - Equivocal >10 - Positive	
Anti-CCP IgG	1.0 U/mL	Negative	<7 - Negative 7-10 - Equivocal >10 - Positive	
Note: This assessment is associated with an increased likelihood of SLE.				

Approved by: Richard Safrin, MD

Richard E Safrin MD

Date: 1-25-2023

Results were obtained using flow cytometry for complement C4d fragment bound to erythrocytes (EC4d) and B-lymphocytes (BC4d). Autoantibodies were determined using solid phase immunoassays. ANA was determined by indirect immunofluorescence and solid phase assays. ANA by solid phase assay was used for the index calculation. In a study of 794 subjects comprising 304 SLE patients, 285 patients with other rheumatic diseases and 205 normal healthy controls, positivity for Tier 1 markers (anti-dsDNA, confirmed using Crithidia, anti-Sm or elevated EC4d and BC4d) was associated with a sensitivity of 46% and a specificity of 97%. Among the 440 subjects negative in Tier 1, a positive index score composite of ANA (by ELISA), EC4d/BC4d and positivity for anti-citrullinated peptide antibodies, SS-B/La, CENP, Jo-1 or Scl-70 resulted in sensitivity of 62% for SLE and specificity of 89%. Two tier combination yielded 80% sensitivity for SLE and 86% specificity for other rheumatic diseases (98% specificity vs. healthy).



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SLE-Associated Analytes	Value	Interpretation	Reference Range
+ ANA IgG	40.00 Units	POSITIVE	ELISA: <20 - Negative 20-<60 - Positive ≥60 - Strong Positive
+ ANA by HEp-2	Titer: 1:320	POSITIVE	IFA: <1:80 - Negative ≥1:80 - Positive
	Nuclear Pattern: Speckled Cytoplasmic Pattern: Not Observed		
Anti-dsDNA IgG	20.00 IU/mL	Negative	ELISA: <201 - Negative 201-<302 - Equivocal ≥302 - Positive
Confirmation by Crithidia luciliae	N/A		IFA: Negative
Anti-Smith IgG	1.0 U/mL	Negative	ELFA: <7 - Negative 7-10 - Equivocal >10 - Positive
+ CB-CAP: EC4d - Erythrocyte-bound C4d	25 Net MFI	POSITIVE	FACS: <15 - Negative 15-75 - Positive >75 - Strong Positive
+ CB-CAP: BC4d - B-lymphocyte-bound C4d	100 Net MFI	POSITIVE	FACS: <61 - Negative 61-200 - Positive >200 - Strong Positive

Other Autoimmune Disease Auto-Antibodies	Value	Interpretation	Reference Range
+ Anti-U1RNP IgG	20.0 U/mL	POSITIVE	ELFA: <5 - Negative 5-10 - Equivocal >10 - Positive
Anti-RNP70 IgG	5.0 U/mL	Negative	ELFA: <7 - Negative 7-10 - Equivocal >10 - Positive
Anti-Ro52 IgG	5.0 U/mL	Negative	ELFA: <7 - Negative 7-10 - Equivocal >10 - Positive
Anti-Ro60 IgG	5.0 U/mL	Negative	ELFA: <7 - Negative 7-10 - Equivocal >10 - Positive
Anti-SS-B/La IgG	1.0 U/mL	Negative	ELFA: <7 - Negative 7-10 - Equivocal >10 - Positive
Anti-Scl-70 IgG	1.0 U/mL	Negative	ELFA: <7 - Negative 7-10 - Equivocal >10 - Positive
Anti-RNA Pol III IgG	4.0 U/mL	Negative	ELFA: <7 - Negative 7-10 - Equivocal >10 - Positive
Anti-Centromere Protein B (CENP) IgG	1.0 U/mL	Negative	ELFA: <7 - Negative 7-10 - Equivocal >10 - Positive
Anti-Jo-1 IgG	1.0 U/mL	Negative	ELFA: <7 - Negative 7-10 - Equivocal >10 - Positive

Rheumatoid Arthritis Auto-Antibodies	Value	Interpretation	Reference Range
Rheumatoid Factor IgM	2.0 IU/mL	Negative	ELFA: <3.5 - Negative 3.5-5 - Equivocal >5 - Positive
Rheumatoid Factor IgA	1.0 IU/mL	Negative	ELFA: <14 - Negative 14-20 - Equivocal >20 - Positive
Anti-CCP IgG	1.0 U/mL	Negative	ELFA: <7 - Negative 7-10 - Equivocal >10 - Positive

Antiphospholipid Syndrome Auto-Antibodies	Value	Interpretation	Reference Range
Anti-Cardiolipin IgM	2.0 U/mL	Negative	ELFA: <10 - Negative 10-40 - Weak Positive >40 - Positive
Anti-Cardiolipin IgG	4.0 U/mL	Negative	ELFA: <10 - Negative 10-40 - Weak Positive >40 - Positive
Anti-β2 Glycoprotein 1 IgM	3.0 U/mL	Negative	ELFA: <7 - Negative 7-10 - Equivocal >10 - Positive
Anti-β2 Glycoprotein 1 IgG	2.0 U/mL	Negative	ELFA: <7 - Negative 7-10 - Equivocal >10 - Positive

Thyroid Auto-Antibodies	Value	Interpretation	Reference Range
Anti-Thyroglobulin IgG	<12 IU/mL	Negative	ELFA: <40 - Negative 40-60 - Equivocal >60 - Positive
Anti-Thyroid Peroxidase IgG	<4 IU/mL	Negative	ELFA: <25 - Negative 25-35 - Equivocal >35 - Positive

Notes:

References

1) Kalunian K, et al. Measurement of CB-CAPs enhances diagnostic performance in SLE. Arthritis Rheum. 2012 Dec;64(12):4040-7. 2) Wallace D, et al. Systemic lupus erythematosus and primary fibromyalgia can be distinguished by testing for cell-bound complement activation products. Lupus Sci Med., 2016 Feb;3(1):e000127. 3) Putterman C, et al. CB-CAPS in SLE: comparison with anti-ds DNA and standard complement measurements. Lupus Sci Med. 2014 Oct;1(1):e000056



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