



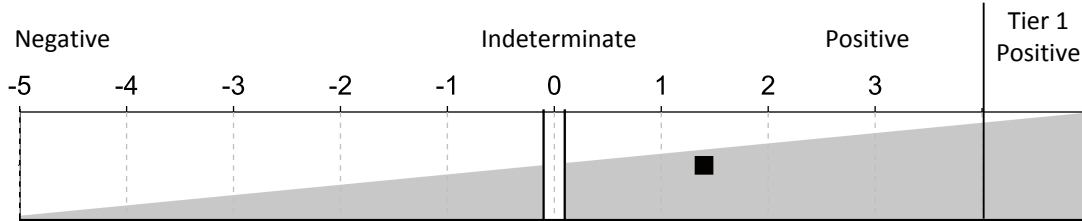
Order ID 739811
 Provider Exagen Provider MD

Specimen
 Collected 01/15/2022
 Received 01/16/2022
Test Order
 Created 01/16/2022
 Reported 01/20/2022

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

AVISE Lupus 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	<0.7 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: 01-20-2022

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
Anti-dsDNA by Crithidia (confirmatory)	N/A		IFA: Negative
Anti-Smith IgG	<0.7 U/mL	Negative	ELISA: <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-SS-B/La IgG	1.0 U/mL	Negative	ELISA: <7 - Negative 7-10 - Equivocal >10 - Positive
Anti-Scl-70 IgG	1.0 U/mL	Negative	ELISA: <7 - Negative 7-10 - Equivocal >10 - Positive
Anti-Centromere Protein B (CENP) IgG	1.0 U/mL	Negative	ELISA: <7 - Negative 7-10 - Equivocal >10 - Positive
Anti-Jo-1 IgG	1.0 U/mL	Negative	ELISA: <7 - Negative 7-10 - Equivocal >10 - Positive
Anti-CCP IgG	1.0 U/mL	Negative	ELISA: <7 - Negative 7-10 - Equivocal >10 - Positive

Optional Analytes Ordered	Value	Interpretation	Reference Range
No optional analytes ordered			

Notes:

References

1. Kalunian K, et al. Measurement of cell-bound complement activation products enhances diagnostic performance in systemic lupus erythematosus. 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. Cell-bound complement activation products in systemic lupus erythematosus: comparison with anti-double-stranded DNA and standard complement measurements. Lupus Sci Med. 2014 Oct;1(1):e000056



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