



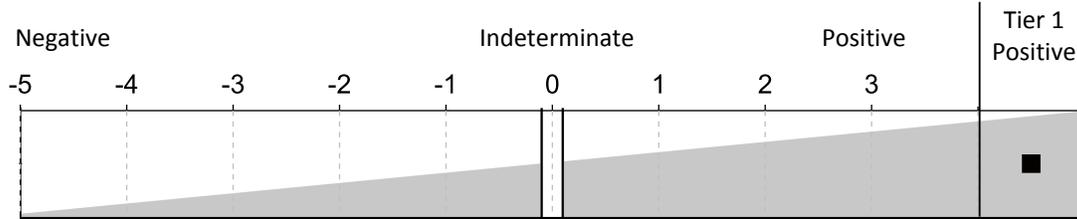
Order ID B26371  
 Provider Sample Provider MD

**Specimen**  
 Collected 09/23/2024  
 Received 09/24/2024  
**Test Order**  
 Created 09/24/2024  
 Reported 09/27/2024

**Patient**  
**Sample, Susan**  
 Gender - DOB Female - 01/01/2001  
 MRN MRN12345

## AVISE Lupus Test Report

AVISE Lupus Result: **Tier 1 Positive**



Tier 1 Analytes	Value	Interpretation	Reference Range	Tier 1 Assessment
Anti-dsDNA IgG	865.61 IU/mL	POSITIVE	<201 - Negative   201-<302 - Equivocal   ≥302 - Positive	Positive
Confirmation by Crithidia luciliae		Positive anti-dsDNA confirmed by Crithidia		
Anti-Smith IgG	1.2 U/mL	Negative	<7 - Negative   7-10 - Equivocal   >10 - Positive	
CB-CAP: EC4d - Erythrocyte-bound C4d	18 Net MFI	POSITIVE	<15 - Negative   15 -75 - Positive   >75 - Strong Positive	
CB-CAP: BC4d - B-lymphocyte-bound C4d	52 Net MFI	Negative	<61 - Negative   61-200 - Positive   >200 - Strong Positive	
<b>Note:</b> The Tier 1 result is associated with an increased likelihood of SLE and is the product of the following analyte values meeting the Tier 1 criteria: Anti-dsDNA, confirmed by Crithidia IFA				

Tier 2 Analytes	Value	Interpretation	Reference Range	Tier 2 Assessment
ANA IgG	120.88 Units	STRONG POSITIVE	<20 - Negative   20-<60 - Positive   ≥60 - Strong Positive	Not assessed due to Tier 1 Positive
CB-CAP: EC4d - Erythrocyte-bound C4d	18 Net MFI	POSITIVE	<15 - Negative   15-75 - Positive   >75 - Strong Positive	
CB-CAP: BC4d - B-lymphocyte-bound C4d	52 Net MFI	Negative	<61 - Negative   61-200 - Positive   >200 - Strong Positive	
Anti-SS-B/La IgG	1.7 U/mL	Negative	<7 - Negative   7-10 - Equivocal   >10 - Positive	
Anti-Scl-70 IgG	0.8 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	<0.3 U/mL	Negative	<7 - Negative   7-10 - Equivocal   >10 - Positive	
Anti-CCP IgG	1.4 U/mL	Negative	<7 - Negative   7-10 - Equivocal   >10 - Positive	
<b>Note:</b>				

Approved by: Prashanti Reddy, M.D.

*Prashanti Reddy MD*

Date: 2024-09-27

Results were obtained using Flow Cytometry for complement C4d fragment bound to erythrocytes (EC4d) and B-lymphocytes (BC4d). Results were obtained by Enzyme Linked Immunosorbent Assay (ELISA) and Indirect immunofluorescence Assay (IFA) for determination of ANA. ANA by ELISA 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 by ELISA, confirmed Crithidia by indirect immunofluorescence, anti-Sm by Enzyme Linked Fluorescent Immunoassay (ELFA) or elevated EC4d and BC4d by Flow Cytometry) 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-CCP, SS-B/La, CENP, Jo-1 or Scl-70 (by ELFA) 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
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++ ANA IgG	120.88 Units	STRONG POSITIVE	ELISA: <20 - Negative   20-<60 - Positive   ≥60 - Strong Positive
+ ANA by HEp-2	Titer: 1:640	POSITIVE	IFA: <1:80 - Negative   ≥1:80 - Positive
Nuclear Pattern: Homogeneous Cytoplasmic Pattern: Not Observed			
+ Anti-dsDNA IgG	865.61 IU/mL	POSITIVE	ELISA: <201 - Negative   201-<302 - Equivocal   ≥302 - Positive
+ Confirmation by Crithidia luciliae	POSITIVE		IFA: Negative
Anti-Smith IgG	1.2 U/mL	Negative	ELFA: <7 - Negative   7-10 - Equivocal   >10 - Positive
+ CB-CAP: EC4d - Erythrocyte-bound C4d	18 Net MFI	POSITIVE	FACS: <15 - Negative   15-75 - Positive   >75 - Strong Positive
CB-CAP: BC4d - B-lymphocyte-bound C4d	52 Net MFI	Negative	FACS: <61 - Negative   61-200 - Positive   >200 - Strong Positive

Other Autoimmune Disease Auto-Antibodies	Value	Interpretation	Reference Range
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Anti-SS-B/La IgG	1.7 U/mL	Negative	ELFA: <7 - Negative   7-10 - Equivocal   >10 - Positive
Anti-Scl-70 IgG	0.8 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	<0.3 U/mL	Negative	ELFA: <7 - Negative   7-10 - Equivocal   >10 - Positive
Anti-CCP IgG	1.4 U/mL	Negative	ELFA: <7 - Negative   7-10 - Equivocal   >10 - Positive

Optional Analytes Ordered	Value	Interpretation	Reference Range
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No optional analytes ordered

**Notes:**

**References**

- Ramsey-Goldman R, et al. ACR Open Rheumatol. 2021 Feb;3(2):116-123. doi: 10.1002/acr2.11219.
- Arriens C, et al. Lupus Sci Med. 2020 Apr;7(1). doi: 10.1136/lupus-2019-000377.
- Ramsey-Goldman R, et al. Arthritis Rheumatol. 2020 Jan;72(1):78-88. doi: 10.1002/art.41093.
- Hui-Yuen J, et al. Lupus. 2018 Dec;27(14):2262-2268. doi: 10.1177/0961203318809181.
- Wallace D, et al. Lupus Sci Med. 2016 Feb;3(1):e000127. doi: 10.1136/lupus-2015-000127.
- Putterman C, et al. Lupus Sci Med. 2014 Oct;1(1):e000056. doi: 10.1136/lupus-2014-000056.



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