



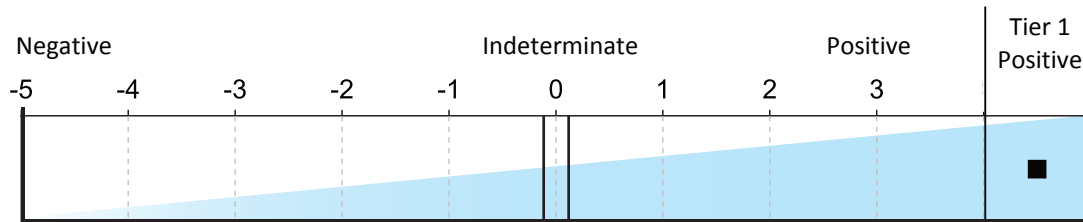
Order ID 531749  
 Provider Example Provider MD

**Specimen**  
 Collected 03/02/2020  
 Received 03/03/2020  
**Test Order**  
 Created 03/03/2020  
 Reported 03/04/2020

**Patient**  
**Sample, Wanda S**  
 Gender - DOB Female - 01/24/1974  
 Identifier Received  
 Exagen ID 302261

## AVISE CTD Test Report

AVISE Lupus Result: **Tier 1 Positive**



Tier 1 Analytes	Value	Interpretation	Reference Range	Tier 1 Assessment
Anti-dsDNA IgG Confirmation by Crithidia luciliae	600 IU/mL	POSITIVE	<302 - Negative   ≥302 - Positive	Positive
Anti-Smith IgG	3 U/mL	Negative	<5 - Negative   5-10 - 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	
<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 IgG				

Tier 2 Analytes	Value	Interpretation	Reference Range	Tier 2 Assessment
ANA IgG	90 Units	STRONG POSITIVE	<20 - Negative   20-59 - Positive   ≥60 - Strong Positive	Not assessed due to Tier 1 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 U/mL	Negative	<7 - Negative   7-10 - Equivocal   >10 - Positive	
Anti-Scl-70 IgG	<1 U/mL	Negative	<7 - Negative   7-10 - Equivocal   >10 - Positive	
Anti-Centromere Protein B (CENP) IgG	1 U/mL	Negative	<7 - Negative   7-10 - Equivocal   >10 - Positive	
Anti-Jo-1 IgG	<1 U/mL	Negative	<7 - Negative   7-10 - Equivocal   >10 - Positive	
Anti-CCP IgG	4 U/mL	Negative	<7 - Negative   7-10 - Equivocal   >10 - Positive	
<b>Note:</b>				

### Test Method Description

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
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++ ANA IgG	90 Units	STRONG POSITIVE	ELISA: <20 - Negative   20-59 - Positive   ≥60 - Strong Positive
+ ANA by HEp-2	Titer: 1:320	POSITIVE	IFA: <1:80 - Negative   ≥1:80 - Positive
Nuclear Pattern: Homogeneous Cytoplasmic Pattern: Not Observed			
+ Anti-dsDNA IgG	600 IU/mL	POSITIVE	ELISA: <302 - Negative   ≥302 - Positive
+ Anti-dsDNA by Crithidia (confirmatory)	POSITIVE		IFA: Negative
Anti-Smith IgG	3 U/mL	Negative	ELISA: <5 - Negative   5-10 - 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
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Anti-U1RNP IgG	3 U/mL	Negative	ELISA: <7 - Negative   7-10 - Equivocal   >10 - Positive
Anti-RNP70 IgG	1 U/mL	Negative	ELISA: <7 - Negative   7-10 - Equivocal   >10 - Positive
Anti-Ro52 IgG	8 CU	Negative	CIA: <20 - Negative   ≥20 - Positive
Anti-Ro60 IgG	5 CU	Negative	CIA: <20 - Negative   ≥20 - Positive
Anti-SS-B/La IgG	1 U/mL	Negative	ELISA: <7 - Negative   7-10 - Equivocal   >10 - Positive
Anti-Scl-70 IgG	<1 U/mL	Negative	ELISA: <7 - Negative   7-10 - Equivocal   >10 - Positive
Anti-RNA Pol III IgG	15 Units	Negative	ELISA: <20 - Negative   20 - 80 - Positive   >80 - Strong Positive
Anti-Centromere Protein B (CENP) IgG	1 U/mL	Negative	ELISA: <7 - Negative   7-10 - Equivocal   >10 - Positive
Anti-Jo-1 IgG	<1 U/mL	Negative	ELISA: <7 - Negative   7-10 - Equivocal   >10 - Positive

Rheumatoid Arthritis Auto-Antibodies	Value	Interpretation	Reference Range
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Rheumatoid Factor IgM	2.0 U/mL	Negative	ELISA: <3.5 - Negative   3.5-5 - Equivocal   >5 - Positive
Rheumatoid Factor IgA	1 U/mL	Negative	ELISA: <14 - Negative   14-20 - Equivocal   >20 - Positive
Anti-CCP IgG	4 U/mL	Negative	ELISA: <7 - Negative   7-10 - Equivocal   >10 - Positive

Antiphospholipid Syndrome Auto-Antibodies	Value	Interpretation	Reference Range
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Anti-Cardiolipin IgM	2 CU	Negative	CIA: <20 - Negative   ≥20 - Positive
Anti-Cardiolipin IgG	<6 CU	Negative	CIA: <20 - Negative   ≥20 - Positive
Anti-β2 Glycoprotein 1 IgM	2 CU	Negative	CIA: <21 - Negative   ≥21 - Positive
Anti-β2 Glycoprotein 1 IgG	<6 CU	Negative	CIA: <21 - Negative   ≥21 - Positive

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