

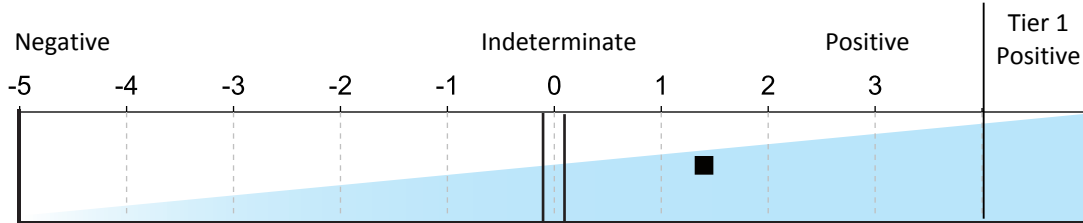
Order ID 200432
Provider Example Provider MD

Specimen
Collected 05/30/2016
Received 05/16/2016
Test Order
Created 06/01/2016
Reported 06/02/2016

Patient
Sample, Nancy S
Gender - DOB Female - 01/25/1974
Identifier Received
Exagen ID 300955

AVISE Lupus Test Report

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



Tier 1 Analytes	Value	Interpretation	Reference Range	Tier 1 Assessment
Anti-dsDNA IgG Confirmation by Crithidia luciliae	20 IU/mL	Negative	<302 - Negative ≥302 - Positive	Negative
Anti-Smith IgG	<1 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	
Note: Criteria for Tier 1 Positive not met.				

Tier 2 Analytes	Value	Interpretation	Reference Range	Tier 2 Assessment
ANA IgG	40 Units	POSITIVE	<20 - Negative 20-59 - 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 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-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	2 U/mL	Negative	<7 - Negative 7-10 - Equivocal >10 - Positive	
Note: This assessment is associated with an increased likelihood of SLE.				

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).

SLE-Associated Analytes	Value	Interpretation	Reference Range
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+ ANA IgG	40 Units	POSITIVE	ELISA: <20 - Negative 20-59 - Positive ≥60 - Strong Positive
+ HEp-2 cell fluorescence	Titer: 1:320	POSITIVE	IFA: <1:80 - Negative ≥1:80 - Positive
Nuclear Pattern: Homogeneous Cytoplasmic Pattern: Not Observed			
Anti-dsDNA IgG	20 IU/mL	Negative	ELISA: <302 - Negative ≥302 - Positive
Anti-dsDNA - confirmatory	N/A		IFA - using Crithidia luciliae
Anti-Smith IgG	<1 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-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-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
Anti-CCP IgG	2 U/mL	Negative	ELISA: <7 - Negative 7-10 - Equivocal >10 - Positive

Optional Analytes Ordered	Value	Interpretation	Reference Range
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No optional analytes ordered

Notes:

References

1. Thermo Fisher/Connective Tissue Markers references and results (Phadia product inserts).
2. Manzi S et al. Measurement of erythrocyte C4d and complement receptor 1 in systemic lupus erythematosus. Arthritis Rheum, 50(11):3596-604. 2004.
3. Kalunian et al. Measurement of cell-bound complement activation products enhances diagnostic performance in systemic lupus erythematosus. Arthritis Rheum. 2012 Dec;64(12):4040-7.
4. Putterman et al. An Assay Panel Combining Cell Bound Complement Activation Products With Autoantibodies To Extractable Nuclear Antigens and Mutated Citrullinated Vimentin Helps With The Differential Diagnosis Of Systemic Lupus Erythematosus. Arthritis Rheumatism 2013 Suppl (S2525).