AVISE® SLE Monitor

Order ID A00326
Provider Exagen Provider MD

Specimen
Collected 11/01/2023
Received 11/02/2023

Test Order
Created 11/02/2023
Reported 11/06/2023

Patient
Sample, Susan
Gender - DOB Female - 01/01/1996
Identifier Received
Exagen ID 997704

AVISE SLE Monitor Test Report

	Value	Interpretation	Reference Range
Complement Component			
+ EC4d - Erythrocyte-bound C4d	20 Net MFI	POSITIVE	FACS: <15 - Negative | ≥15 - Positive
Complement C3	105.120 mg/dL	Normal	Turbidimetry: 81 - 157 - Normal
Complement C4	25.025 mg/dL	Normal	Turbidimetry: 13 - 39 - Normal
Antibody Component			
+ Anti-dsDNA IgG	59.9 IU/mL	POSITIVE	CIA: <27 - Negative | 27 - 35 - Indeterminate | >35 - Positive
+ Anti-C1q IgG	29.8 Units	POSITIVE	ELISA: <20 - Negative | ≥20 - Positive

Analyte Descriptions

EC4d

Erythrocyte-bound C4d (EC4d) measured by flow cytometry has been shown to significantly correlate with disease activity as measured by clinical SELENA-SLEDAI [1,2]. Furthermore, reductions in EC4d levels have been shown to correlate with improvements in SF-36 score and BILAG-2004 index [2].

Complement C3/C4

Normalization of complement C3 and C4 proteins has been shown to correlate with disease improvements in SLE [1-3].

Anti-dsDNA IgG

Anti-dsDNA is quantified using a bead-based chemiluminescence immunoassay method. Relative to other methods, values produced by this method have superior correlation with disease activity [3,4].

Anti-C1q IgG

Autoantibodies to C1q have been shown to significantly correlate with clinical SELENA-SLEDAI values and are superior to 3 other biomarkers in their association with lupus nephritis and proteinuria [2,3,5].

Test Method Description

The disease monitoring panel consists of C4d bound to erythrocytes (determined by flow cytometry), soluble complement C3c and C4 proteins (determined by immunoturbidimetry), and SLE auto-antibodies (anti-double stranded DNA and anti-C1q IgG, all determined by immunoassays). Changes in EC4d, anti-dsDNA, anti-C1q and complement proteins have been shown to correlate with change in SLE disease activity, as defined by clinical SELENA-SLEDAI, BILAG index score and proteinuria [1-3].

References

1. Kao A, et al. Erythrocyte C3d and C4d for Monitoring Disease Activity in Systemic Lupus Erythematosus. Arthritis and Rheumatism 62[3], 837-844. 2010
2. Buyon J, et al. Reduction in Erythrocyte Bound Complement Activation Products and Titers of Anti-C1q antibodies associate with clinical improvement in systemic lupus erythematosus. Lupus Science & Medicine 2016
3. Merrill J, et al. Erythrocyte-bound C4d in combination with complement and autoantibody status for the monitoring of SLE. Lupus Sci Med. 2018;5(1):e000263
4. Mahler M, et al. Performance Characteristics of Different Anti-Double-Stranded DNA Antibody Assays in the Monitoring of Systemic Lupus Erythematosus. J Immunol Res. 2017;2017:1720902.
5. Orbai A, et al. Anti-C1q Antibodies in Systemic Lupus Erythematosus. Lupus. 2015 January; 24(1): 42–49
6. Petri M, et al. Complement C4d Split Products in Combination with Lupus Anticoagulant and Low Complement Associate with Thrombosis in Systemic Lupus Erythematosus [abstract]. Arthritis Rheumatol. 2018; 70 (suppl 10).
7. Lood C et al. Platelet activation and anti-phospholipid antibodies collaborate in the activation of the complement system on platelets in systemic lupus erythematosus. PLoS One. 2014; doi: 10.1371/journal.pone.0099386. eCollection 2014.
8. Data on file - Exagen Diagnostics, Inc.

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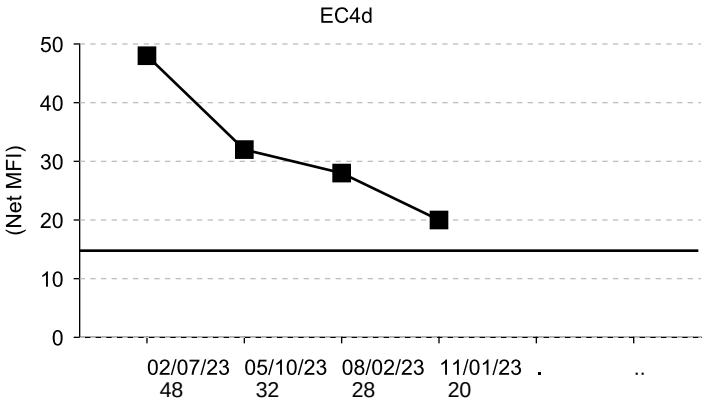
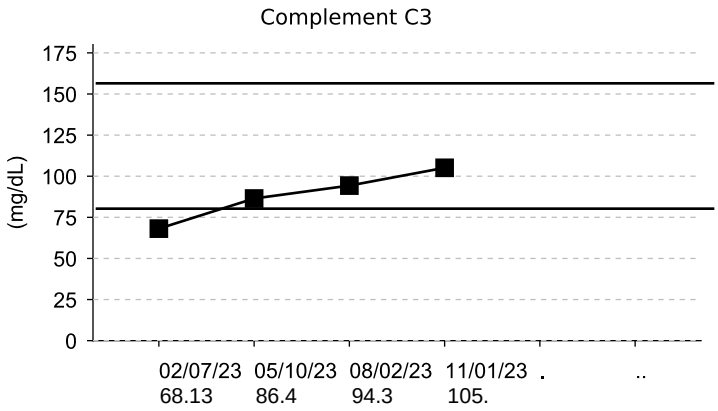
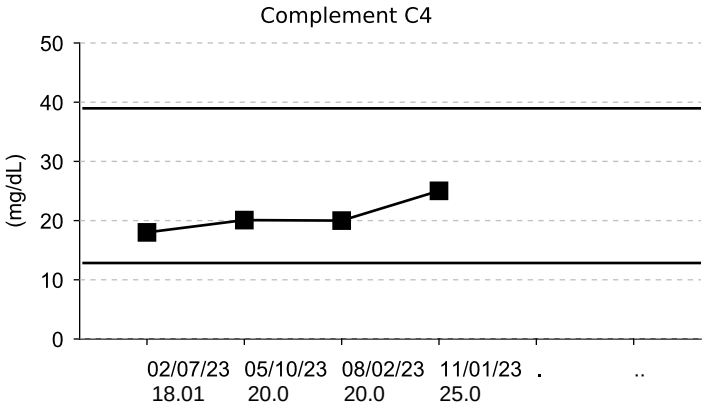
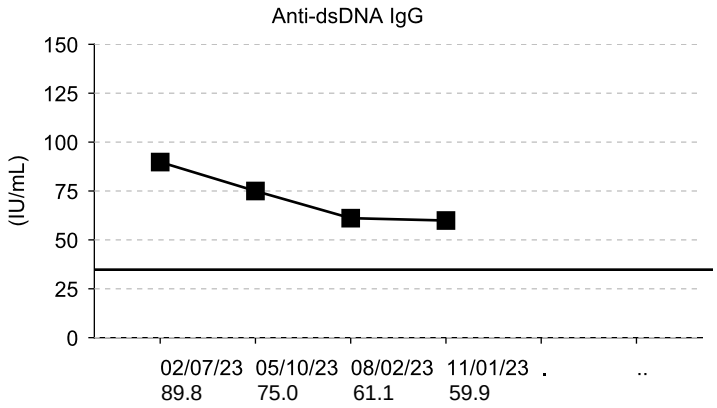
Complement Component

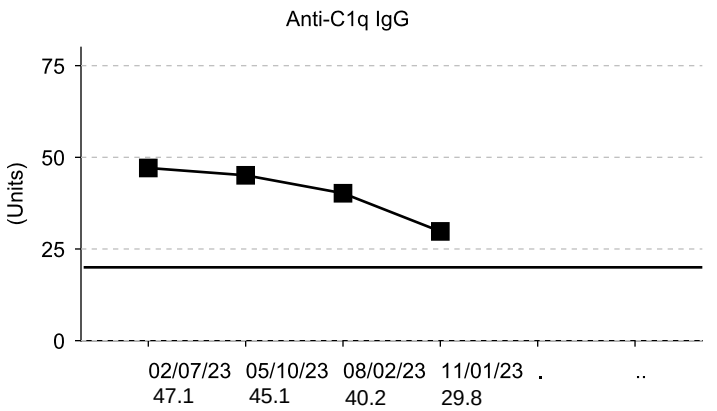






Antibody Component





Exagen®
1261 Liberty Way, Vista CA 92081
CLIA# 05D1075048
CAP# 7201051 | NYSDOH PFI# 8369

Laboratory Directors:
Richard Safrin, MD
R. Harper Summers, MD

Provider Relations: 888.452.1522

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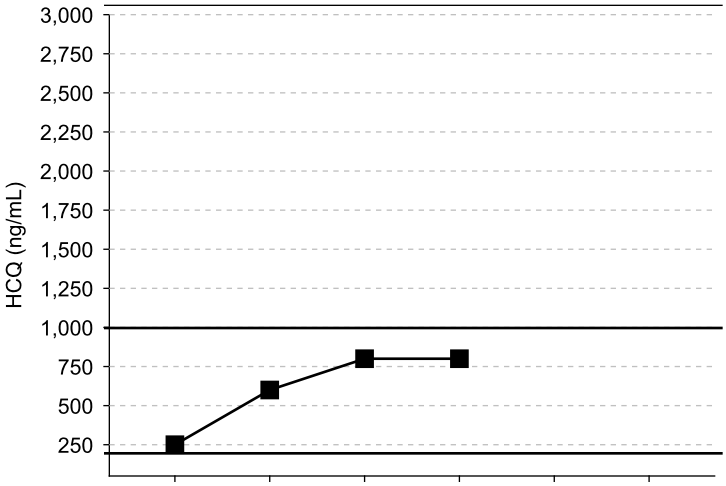
Avise HCQ Test Report

Current Hydroxychloroquine (HCQ) Level:

800.0 ng/mL - Sub-therapeutic

Hours elapsed between last dose and sample collection	HCQ Dose (mg/day)	Date HCQ Dose Initiated

Current and Prior 5 HCQ Levels



Date	02/07/23	05/10/23	08/02/23	11/01/23	.	..
Level (ng/mL)	250.0	600.0	800.0	800.0		
Dose (mg/day)						

HCQ Level	*Interpretation & Consideration*
Therapeutic (>1000 ng/mL)	Level associated with clinical efficacy. HCQ is likely absorbed effectively
Sub-therapeutic (200-1000 ng/mL)	Patient could be partially adherent to therapy. Patients with HCQ lower than 1000 ng/mL can be at greater risk for disease flare
Underexposed (<200 ng/mL)	Patient is likely non-adherent to HCQ therapy

Test Method Description

HCQ concentration is determined by liquid chromatography coupled with mass spectrometry (LC/MS/MS).
This test has not been validated in pediatric populations. The HCQ blood level should be evaluated after 6 months of HCQ therapy - it has not been validated in patients treated for less than 6 months. This test cannot be used to assess the risk of HCQ toxicity.

References

1. Costedoat-Chalumeau N, et al. Low blood concentration of hydroxychloroquine is a marker for and predictor of disease exacerbations in patients with systemic lupus erythematosus. Arthritis Rheum. 2006 Oct;54(10):3284-90.
2. Costedoat-Chalumeau N, et al. Very low blood hydroxychloroquine concentration as an objective marker of poor adherence to treatment of systemic lupus erythematosus. Ann Rheum Dis. 2007 Jun;66(6):821-4.
3. Costedoat-Chalumeau N, et al. (2013a) Hydroxychloroquine in Systemic Lupus Erythematosus: Results of a French Multicentre Controlled Trial (PLUS Study). Ann Rheum Dis 72:1786-1792.
4. Costedoat-Chalumeau N, et al. (2013b) Adherence to Treatment in Systemic Lupus Erythematosus Patients. Best Pract Res Clin Rheumatol 27:329-340.
5. Frances C, et al. Low blood concentration of hydroxychloroquine in patients with refractory cutaneous lupus erythematosus: a French multicenter prospective study. Arch Dermatol. 2012 Apr;148(4):479-84.
6. Exagen Diagnostics, Inc. Date on File.

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