



Sample Test Report

Specimen	Patient
Collected 10/06/2018	Patient, Example L
Received 10/07/2018	
Test Order	Gender - DOB Female - 01/12/1970
Created 10/07/2018	Identifier Received
Reported 10/09/2018	Exagen ID 300955

AVISE SLE Monitor Test Report

	Value	Interpretation	Reference Range
Complement Component			
+ EC4d - Erythrocyte-bound C4d	48 Net MFI	POSITIVE	FACS: <15 - Negative ≥15 - Positive
! Complement C3	68 mg/dL	ABNORMAL - LOW	Turbidimetry: 81 - 157 - Normal
Complement C4	18 mg/dL	Normal	Turbidimetry: 13 - 39 - Normal
Antibody Component			
+ Anti-dsDNA IgG	90 IU/mL	POSITIVE	CIA: <27 - Negative 27 - 35 - Indeterminate ≥36 - Positive
+ Anti-C1q IgG	47 Units	POSITIVE	ELISA: <20 - Negative ≥20 - Positive
Thrombosis-associated Marker			
+ PC4d - Platelet-bound C4d		POSITIVE - confirmation required with new specimen	
Therapy Monitoring			
Hydroxychloroquine	250 ng/mL	Sub-therapeutic	

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].

PC4d

Elevated (positive) platelet-bound C4d (PC4d) levels have been associated with a history of thrombosis in lupus [6,7,8]. Patients with persistent elevated PC4d have been shown to have significant association with thrombosis [6,9].

Test Method Description

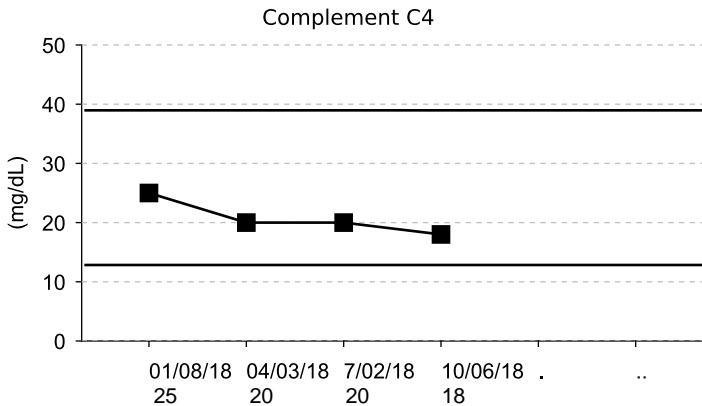
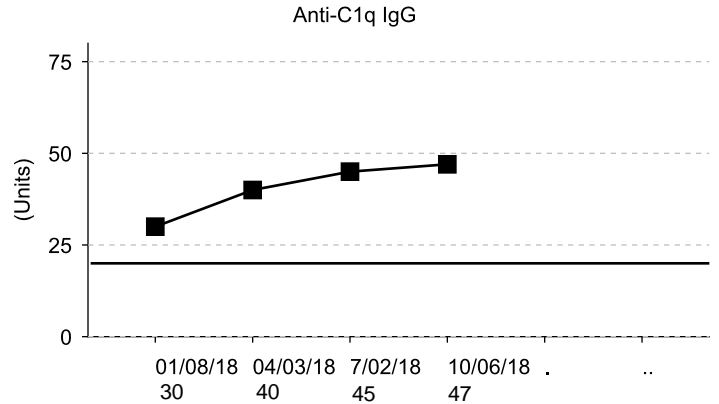
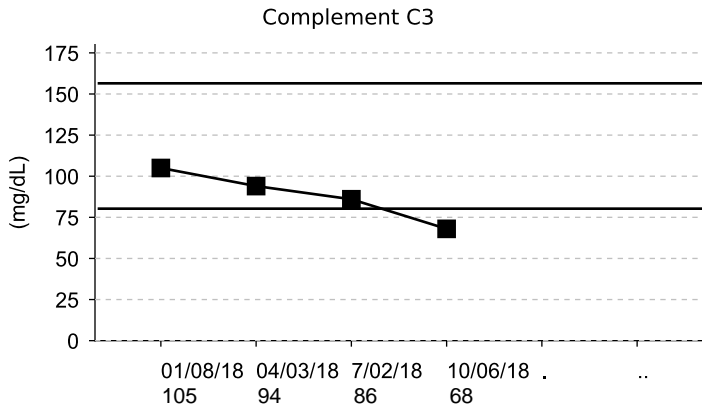
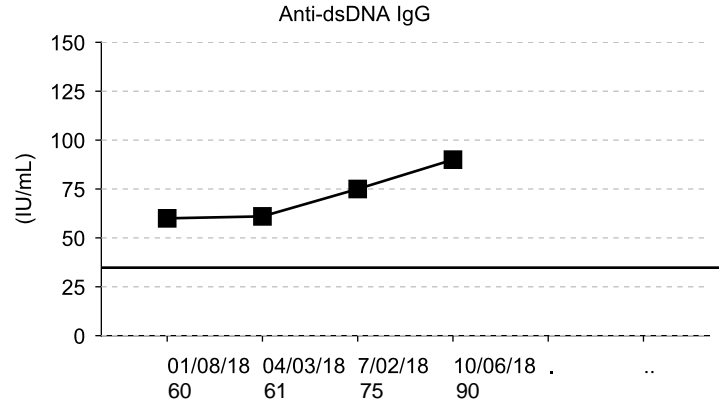
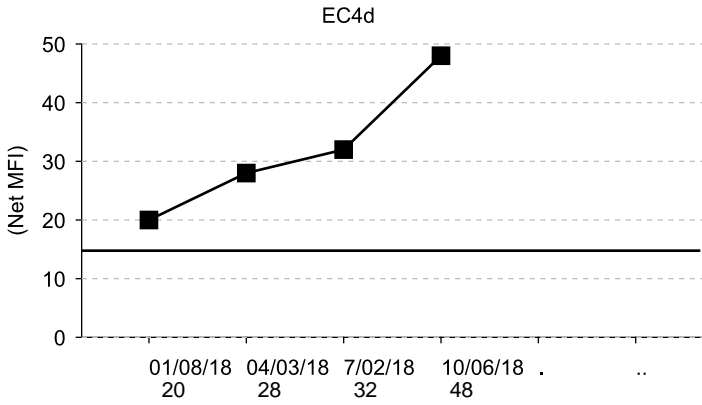
The disease monitoring panel consists of C4d bound to erythrocytes or platelets (determined by flow cytometry), soluble complement C3c and C4 proteins (determined by immunoturbidimetry), and SLE auto-antibodies (anti-double stranded DNA and anti-C1q IgG, all determined by immunoassays). Changes in EC4d, 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

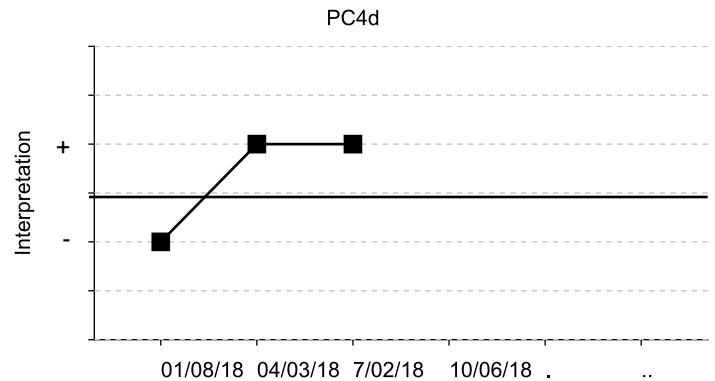
- Kao A, et al. Erythrocyte C3d and C4d for Monitoring Disease Activity in Systemic Lupus Erythematosus. Arthritis and Rheumatism 62[3], 837-844. 2010
- Buyon J, et al. Reduction in Erythrocyte Bound Complement Activation Products and Titers of Anti-C1q antibodies associate with clinical improvement in systemic lupus erythematosus. Lupus Science & Medicine 2016
- 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
- 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.
- Orbai A, et al. Anti-C1q Antibodies in Systemic Lupus Erythematosus. Lupus. 2015 January; 24(1): 42-49
- Kao A, et al. Relation of platelet C4d with all-cause mortality and ischemic stroke in patients with systemic lupus erythematosus. Transl Stroke Res. 2014 Aug;5(4):510-8
- 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).
- 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.
- Data on file - Exagen Diagnostics, Inc

Complement Component

Antibody Component



Thrombosis-associated Marker



Confirmation required with new specimen



Order ID 200432
 Provider Example Provider MD

Specimen
 Collected 10/06/2018
 Received 10/07/2018
Test Order
 Created 10/07/2018
 Reported 10/09/2018

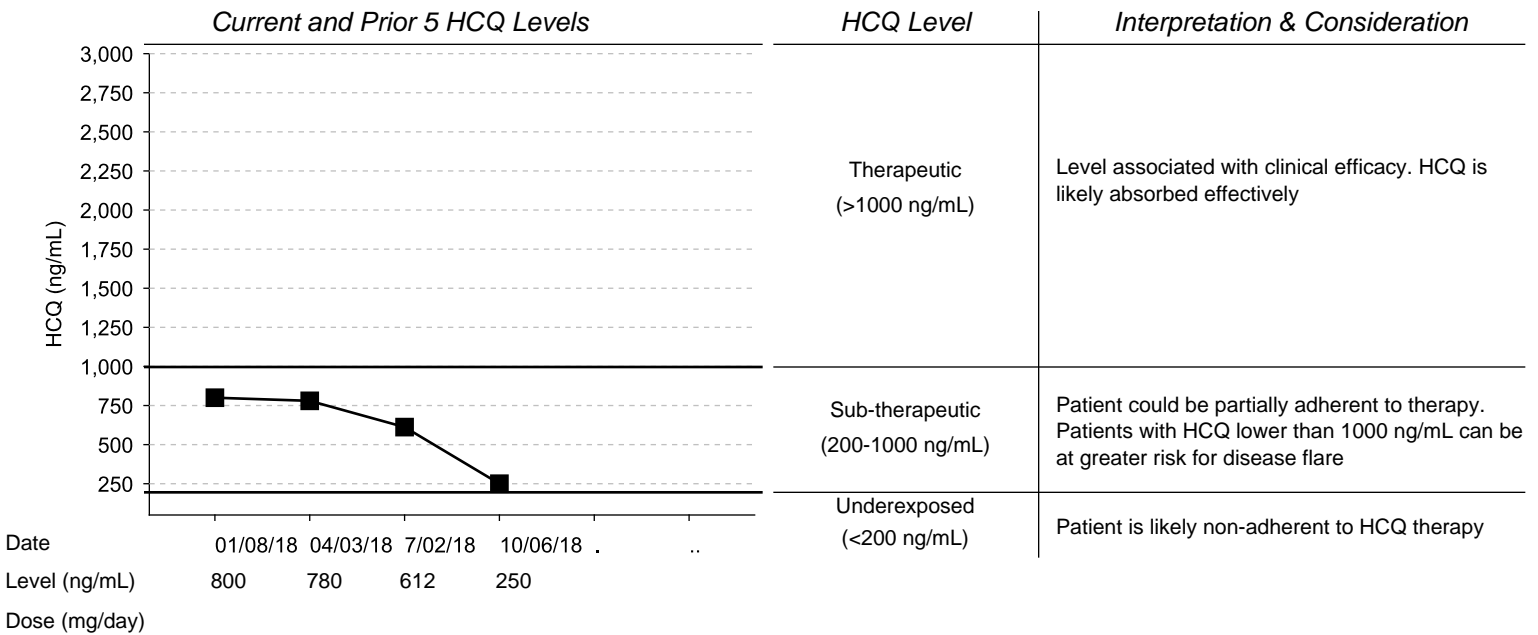
Patient
Patient, Example L
 Gender - DOB Female - 01/12/1970
 Identifier Received
 Exagen ID 300955

AVISE HCQ Test Report

Current Hydroxychloroquine (HCQ) Level:

250 ng/mL - Sub-therapeutic

HCQ Dose (mg/day)



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

- 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.
- 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.
- 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.
- Costedoat-Chalumeau N, et al. (2013b) Adherence to Treatment in Systemic Lupus Erythematosus Patients. *Best Pract Res Clin Rheumatol* 27:329-340.
- 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.
- Exagen Diagnostics, Inc. Data on File.



1261 Liberty Way, Vista CA
 CLIA# 05D1075048
 CAP# 7201051 | PFI# 8369

Laboratory Directors:
 Richard Safrin, MD
 Thierry Dervieux, PhD, DABCC

Provider Relations: 888.452.1522

AVISE and the AVISE and Exagen logos are registered trademarks of Exagen Diagnostics, Inc. ©2018 All Rights Reserved