Effective Date: October 6, 2025

## **TEST CHANGE**

3-Hydroxy-3-Methylglutaryl Coenzyme A Reductase (HMGCR) Antibody, IgG 2013101. HMGCR

2013101, HMGCR		
Specimen Requirements:		
Patient Preparation:		
Collect:	Serum separator tube (SST).	
Specimen Preparation:	Separate serum from cells ASAP or within 2 hours of collection. Transfer 0.5 mL serum (Min: 0.3 mL) to an ARUP standard transport tube.	
Transport Temperature:	Refrigerated. Also acceptable: Frozen.	
Unacceptable Conditions:	Contaminated, heat-inactivated, clots, fibrin, gross red blood cells, severely lipemic, severely hemolyzed, or severely icteric specimens.	
Remarks:		
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 30 days 1 year (avoid repeated freeze/thaw cycles)	
Methodology:	Semi-Quantitative Chemiluminescent Immunoassay (CLIAEnzyme-Linked Immunosorbent Assay (ELISA)	
Performed:	Mon, Wed, Fri	
Reported:	1- <u>5</u> 15 days	
Note:		
CPT Codes:	<u>82397</u> 83516	
New York DOH Approval Status:	This test is New York DOH approved.	
Interpretive Data:		
IgG antibodies to 3-hydroxy-3-methylglutaryl-coenzyme A reductase (HMGCR) are mainly associated with necrotizing autoimmune myopathy (NAM) in a subset of statin-treated patients. Although infrequent, these antibodies may also be observed in statin-naive patients with NAM. Strong clinical correlation is recommended in the absence of muscle fiber necrosis, elevated serum creatine kinase, perimysial pathology, and/or statin exposure.		
Reference Interval:		
	<u>Components</u>	Reference Interval
HMGCR Antibody, IgG	<u>Less than 20.0</u> 0-19 Units: Negative	

Inserted Cells
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 $\label{thm:continuous} \mbox{HOTLINE NOTE: There is a numeric map change associated with this test. Refer to the Hotline Test Mix for interface build information.}$