TEST CHANGE

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

2013101, HMGCR

Specimen Requirements:	
Patient Preparation:	
Collect:	Serum separator tube~~Separator Tube~~ (SST).
Specimen Preparation:	Separate serum from cells ASAP or within 2 hours of collection. Transfer 0.5 mL serum ~~to an ARUP Standard Transport Tube.~~ (Min: 0.3~~1~~5 mL) to an ARUP standard transport tube.
Transport Temperature:	Refrigerated. Also acceptable: Frozen.
Unacceptable Conditions:	~~Other body fluids.~~ Contaminated, heat-inactivated, clots, fibrin, gross red blood cells, severely lipemic, severely hemolyzed, ~~grossly icteric,~~ or severely ~~l~~ict~~p~~er~~m~~ic specimens.
Remarks:	
Stability:	After separation from cells: Ambient: 48 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles)
Methodology:	Semi-Quantitative Enzyme-Linked Immunosorbent Assay (ELISA)
Performed:	Fri
Reported:	1-15 days
Note:	
CPT Codes:	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.

~~This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.~~

Reference Interval:

0-19 Units: Negative