TEST CHANGE

SLCO1B1, 1 Variant

2008426, SLCO1B1

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (EDTA) or pink (K2EDTA), or yellow (ACD Solution A or B).
Specimen Preparation:	Transport 3 mL whole blood. (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma or serum. Heparinized specimens. Frozen specimens in glass collection tubes.
Remarks:	
Stability:	Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Methodology:	Polymerase Chain Reaction (PCR)/Fluorescence Monitoring
Performed:	Mon, Thu
Reported:	5-10 days
Note:	
CPT Codes:	81328
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Background Information for *SLCO1B1*, 1 Variant:
Characteristics: Simvastatin is a commonly prescribed hypolipidemic drug used for cholesterol reduction and control. Approximately 1-5 percent of exposed individuals may experience a dose-dependent myopathy (skeletal muscle toxicity). Symptoms may include pain, muscle weakness, and cramps. The organic anion transporter polypeptide 1B1, encoded by *SLCO1B1*, transports active simvastatin acid from the blood stream into the liver. This test detects a common variant that reduces the function of the transporter, resulting in an increased plasma concentration of the drug.
Inheritance: Autosomal co-dominant.
Cause: Simvastatin hypersensitivity reaction is strongly associated with the *SLCO1B1*5* allele. The mechanism is related to changes in the activity of organic anion-transporter polypeptide 1B1 (OATP1B1). The *1 allele (normal transporter function) is presumed when the *5 allele is not detected. One copy of the *5 allele predicts decreased transporter function; two copies of the *5 allele predicts poor transporter function.
Allele Tested: *SLCO1B1**5 (rs4149056, c.521T>C).

Allele Frequency: Middle Eastern 5 percent, Caucasian 1-3 percent, African 0-2 percent, Asian 0-2 percent, Less than 1 percent in other populations.
Clinical Sensitivity: Drug-dependent.
Methodology: Polymerase Chain Reaction (PCR) and Fluorescence Monitoring.
Analytical Sensitivity and Specificity: Greater than 99 percent.
Limitations: Only the targeted *SLCO1B1* variant will be detected. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with statins may be affected by genetic and non-genetic factors that are not detected by this test. This result does not replace the need for therapeutic or clinical monitoring.

Please note the information contained in this report does not contain medication recommendations, and should not be interpreted as recommending any specific medications. Any dosage adjustments or other changes to medications should be evaluated in consultation with a medical provider.

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.

Counseling and informed consent are recommended for genetic testing. Consent forms are available online.

Reference Interval:

By report

HOTLINE NOTE: There is a component change associated with this test. One or more components have been added or removed. Refer to the Hotline Test Mix for interface build information.