500 Chipeta Way, Salt Lake City, Utah 84108-1221 phone: (801) 583-2787, toll free: (800) 522-2787 Julio C. Delgado, MD, MS, Director of Laboratories

Client: Example Client ABC123 123 Test Drive

Salt Lake City, UT 84108 UNITED STATES

Physician: Doctor, Example

Patient: Patient, Example

DOB 10/11/1944
Gender: Female

Patient Identifiers: 01234567890ABCD, 012345

Visit Number (FIN): 01234567890ABCD

Collection Date:

Statin Sensitivity SLCO1B1, 1 Variant

ARUP test code 2008426

Statin Sensitivity SLCO1B1, Specimen

Whole Blood

Statin Sensitivity SLCO1B1,*5 Genotype

*5/Neg

Indication for testing: predict simvastatin sensitivity.

Interpretation: One copy of the SLCO1B1*5 allele was detected; therefore, decreased transporter function is predicted. This patient is at increased risk for muscle toxicity related to simvastatin use. Symptoms of muscle toxicity may include pain, muscle weakness, and cramps. Severe reactions may progress to severe muscle damage with secondary kidney injury.

This result has been reviewed and approved by Yuan Ji, Ph.D.

H=High, L=Low, *=Abnormal, C=Critical



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> BACKGROUND INFORMATION: Statin Sensitivity 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

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 TESTED: Middle Eastern 5 percent, Caucasian 1-3

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.

Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement C: aruplab.com/CS

VERIFIED/REPORTED DATES				
Procedure	Accession	Collected	Received	Verified/Reported
Statin Sensitivity SLCO1B1, Specimen	18-151-114742	5/31/2018 11:30:00 AM	6/1/2018 3:58:45 PM	6/4/2018 5:51:00 PM
Statin Sensitivity SLCO1B1,*5 Genotype	18-151-114742	5/31/2018 11:30:00 AM	6/1/2018 3:58:45 PM	6/4/2018 5:51:00 PM

END OF CHART

H=High, L=Low, *=Abnormal, C=Critical



Patient: Patient, Example ARUP Accession: 18-151-114742 Patient Identifiers: 01234567890ABCD, 012345 Visit Number (FIN): 01234567890ABCD Page 2 of 2 | Printed: 7/2/2018 12:55:22 PM