ARUP LABORATORIES
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Client: Example Client ABC123
123 Test Drive
Salt Lake City, UT 84108
UNITED STATES

Physician: Doctor, Example

Patient: Patient, Example

DOB	Unknown
Gender:	Male
Patient Identifiers:	01234567890ABCD, 012345
Visit Number (FIN):	01234567890ABCD
Collection Date:	00/00/0000 00:00

SLCO1B1, 1 Variant

ARUP test code 2008426

SLCO1B1, 1 Variant, Specimen	Whole Blood
SLCO1B1, 1 Variant,*5 Genotype	*1/*5 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. Recommendations: The FDA recommends against 80 mg/d of simvastatin. Consider a lower dose, or alternate statin. Guidelines for genotype-based dosing are published by the Clinical Pharmacogenetics Implementation Consortium(CPIC) and can be found at: https://cpicpgx.org/ and https://www.pharmgkb.org/. This result has been reviewed and approved by [redacted]

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

BACKGROUND INFORMATION: 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.
ALLELES TESTED:

*1: Indicative of no detected targeted variants and an assumption of functional allele.

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.

EER SLCO1B1

See Note

[redacted]

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

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
SLCO1B1, 1 Variant, Specimen	23-316-101157	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
SLCO1B1, 1 Variant,*5 Genotype	23-316-101157	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
EER SLCO1B1	23-316-101157	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00

END OF CHART