ARUP LABORATORIES
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Jonathan R. Genzen, MD, PhD, Chief Medical Officer

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

Physician: Doctor, Example

Patient: Patient, Example

DOB	[redacted]/2000
Gender:	Female
Patient Identifiers:	01234567890ABCD, 012345
Visit Number (FIN):	01234567890ABCD
Collection Date:	00/00/0000 00:00

HLA-B*57:01 for Abacavir Sensitivity

ARUP test code 2002429

HLA-B*57:01 Specimen	Whole Blood
HLA-B*57:01 Allele	Negative Indication for testing: Considering or recently prescribed abacavir. Interpretation: The HLA-B*57:01 allele was not detected; therefore, this patient is not predicted to be at increased risk for abacavir hypersensitivity. Recommendations: This negative result does not replace the need for therapeutic drug or other clinical monitoring. Abacavir therapy should be discontinued in all individuals with clinically-suspected abacavir hypersensitivity reaction regardless of HLA-B*5701 status. This result has been reviewed and approved by [redacted]

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

BACKGROUND INFORMATION: HLA-B*57:01 for Abacavir Sensitivity

CHARACTERISTICS: Abacavir sulfate is a nucleoside reverse transcriptase inhibitor (NRTI) used for the treatment of HIV. Abacavir hypersensitivity reaction is characterized by fever, rash, malaise, gastrointestinal and respiratory symptoms. Symptoms typically appear within the first six weeks of treatment, worsen with each subsequent abacavir dose, and may be severe or fatal.
INHERTANCE: Autosomal dominant.
CAUSE: Abacavir hypersensitivity is strongly associated with the HLA-B*57:01 allele. The mechanism is related to drug-specific activation of T lymphocyte killer cells.
ALLELE TESTED: Prescense or abscence of the HLA-B*57:01 allele.
ALLELE FREQUENCY: Southwest Asian 11 percent, Other Asian 0-6.7 percent, European 6.8 percent, South American 2.6 percent, Middle Eastern 2.5 percent, Mexican 2.2 percent, African 1 percent.
CLINICAL SENSITIVITY: 100 percent for immunologically confirmed hypersensitivity reaction.
METHODOLOGY: Polymerase Chain Reaction and Fluorescence Monitoring.
ANALYTICAL SENSITIVITY AND SPECIFICITY: Greater than 99 percent.
LIMITATIONS: Alleles other than HLA-B*57:01 will not be evaluated. This test does not distinguish between heterozygote and homozygote carriers. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with abacavir 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 drug or clinical monitoring

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.

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
HLA-B*57:01 Specimen	25-087-400179	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
HLA-B*57:01 Allele	25-087-400179	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00

END OF CHART

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