Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003826 F 12/05/1988 34 Y

Referral Testing

Collected: 09/26/2023 11:16 Received: 09/26/2023 11:16

Test Name	Result	Flag	Ref-Ranges	Units	Site
HLA-B*5701 Associate Variant Genotyping					
HLA-B*5701 Specimen	Whole Blood				ARRL
HLA-B*5701 Genotyping	**Positive**	**AB**			ARRL

Indication for testing: Considering or recently prescribed abacavir.

Interpretation: At least one copy of the HLA-B*57:01 allele was detected; therefore, this patient is at significantly increased risk for abacavir hypersensitivity. Abacavir hypersensitivity reaction may be severe or fatal and often includes fever, rash, malaise, nausea, vomiting, diarrhea and respiratory symptoms.

Recommendations: Avoidance or discontinuation of abacavir is strongly advised. Although 2 percent of HLA-B*57:01 positive individuals are tolerant to abacavir, therapy with an abacavir-containing regimen should only be considered under exceptional circumstances where benefit outweighs risk.

This result has been reviewed and approved by Julio Delgado, M.D., M.S.
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.

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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.
Performed By: ARUP Laboratories
500 Chipeta Way
Salt Lake City, UT 84108
Laboratory Director: Jonathan R. Genzen, MD, PhD
CLIA Number: 46D0523979

Performing Site:
ARRL: ARUP REFERENCE LAB 500 Chipeta Way Salt Lake City UT 841081221

Reported Date: 2023.09.26 11:16 HLB57