MAYO CLINIC LABORATORIES

TEST OBSOLETE

Notification Date: April 16 2019
Effective Date: June 11, 2019

HLA-B 5701 Genotype, Abacavir Hypersensitivity, Blood

Test ID: HLA57

Explanation:
Test HLA57 will become obsolete on June 11, 2019.

*HLA-B*57:01* Genotype, Pharmacogenomics

Test ID: HL57V

Useful for:
Identifying individuals with an increased risk of hypersensitivity reactions to abacavir, based on the presence of the human leukocyte antigen *HLA-B*57:01* allele

Identifying individuals taking pazopanib who have an increased risk of elevated alanine aminotransferase (ALT) levels based of the presence of the human leukocyte antigen *HLA-B*57:01* allele

Methods:
Qualitative Allele-Specific Real-Time Polymerase Chain Reaction (PCR)

Reference Values:

Negative

An interpretive report will be provided.

Specimen Requirements: Submit only 1 of the following specimens:

Specimen Type: Whole blood

Container/Tube: Lavender top (EDTA)

Specimen Volume: 3 mL

Collection Instructions:

1. Invert several times to mix blood.

2. Send specimen in original tube.

Specimen Stability Information: Ambient (preferred) 9 days/Refrigerated 30 days

Specimen Type: Saliva

Supplies: Saliva Swab Collection Kit (T786)

Patient Preparation: Patient should not eat, drink smoke, or chew gum 30 minutes prior to collection.

Container/Tube: Saliva Swab Collection Kit (T786)

Specimen Volume: 1 swab

Collection Instructions: Collect and send specimen per kit instructions.

Specimen Stability Information: Ambient 30 days

Specimen Type: DNA

Container/Tube: 2 mL screw top tube

Specimen Volume: 100 mcL (microliters)

Collection Instructions:

1. The preferred volume is 100 mcL at a concentration of 50 ng/mcL.

2. Include concentration and volume on tube.

Specimen Stability Information: Frozen (preferred) 1 year/Ambient/Refrigerated

Specimen Stability Information:

Specimen Type	Temperature	Time
Varies	Varies	

Cautions:

Samples may contain donor DNA if obtained from patients who received heterologous blood transfusions or allogeneic hematopoietic stem cell transplantation. Results from samples obtained under these circumstances may not accurately reflect the recipient's genotype. For individuals who have received blood transfusions, the genotype usually reverts to that of the recipient within 6 weeks. The impact of hematopoietic stem cell transplantation on risk of abacavir hypersensitivity reactions is not defined in the literature.

The FDA recommends screening for the *HLA-B*57:01* allele before initiating therapy with abacavir. Genotyping is also critical when there is a clinical history of, or when the physician suspects, an abacavir hypersensitivity reaction. However, FDA guidance states that, regardless of *HLA-B*57:01* status, abacavir should be

permanently discontinued if hypersensitivity cannot be ruled out, even when other diagnoses are possible. Although the negative predictive value of the test is high, a negative *HLA-B*57:01* result does not preclude the development of a hypersensitivity response to abacavir and cannot substitute for clinical vigilance whenever abacavir therapy is administered. Since symptoms of abacavir hypersensitivity are often nonspecific and can imitate other conditions commonly seen in HIV patients on antiretroviral therapy, the phenotypic diagnosis of abacavir hypersensitivity can be challenging. There is significant variability among patients identified as hypersensitive to abacavir. Not all individuals who are positive for *HLA-B*57:01* will have a hypersensitivity reaction.

All patients taking pazopanib should have hepatic function monitored, regardless of *HLA-B*57:01* carrier status, and administration of pazopanib should be interrupted, reduced, or discontinued according to recommendations in the FDA label if hepatic function is impaired.

Rare or novel variants may be present that could lead to false-negative or false-positive results. There may be rare or novel HLA-B alleles that could interfere with this assay. There are, as yet, no data indicating whether any other allele or subtypes are associated with abacavir hypersensitivity or pazopanib hepatotoxicity.

CPT Code:
81381

Day(s) Setup: Monday, Wednesday - Friday; 9 a.m.

Analytic Time: 1 day (not reported on Saturday and Sunday

Questions

Contact Heather Flynn Gilmer, Laboratory Technologist Resource Coordinator at 800-533-1710.