

Notification Date: May 10, 2021 Effective Date: June 10, 2021

# Warfarin Response Genotype, Varies

Test ID: WARSQ

### **Useful for:**

Identifying individuals with an increased risk of severe cutaneous adverse reactions to allopurinol based on the presence of the human leukocyte antigen *HLA-B\*58:01* allele

#### Methods:

Real-Time Polymerase Chain Reaction (PCR) with Allelic Discrimination Analysis

#### **Genetics Information:**

This test is used for assessing *CYP2C9*, *VKORC1*, *CYP4F2*, and rs12777823 for variants affecting the metabolism of warfarin (Coumadin). This assay should be ordered on patients who are receiving warfarin for the first time or who are experiencing difficulties in maintaining the international normalized ratio (INR) in the therapeutic range.

## Advisory:

If patient is using medications other than warfarin, the preferred test is 2C9QT / Cytochrome P450 2C9 Genotype, Varies, which tests for only the CYP2C9 gene.

Testing is available as the single gene assay (this test) or as a part of a focused pharmacogenomics panel, which includes testing for the following genes: *CYPs 1A2, 2C9, 2C19, 2D6, 3A4, 3A5, 4F2, SLCO1B1*, and *VKORC1*. Order PGXQP / Focused Pharmacogenomics Panel, Varies if multiple pharmacogenomic genotype testing is desired.

#### **Reference Values:**

An interpretive report will be provided.

# Specimen Stability Information:

Specimen Type	Temperature	Time
Varies	Varies	

## **Specimen Requirements:**

Multiple genotype tests can be performed on a single specimen after a single extraction.

# 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

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

**Supplies:** 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)/Ambient/Refrigerated

## Cautions:

Samples may contain donor DNA if obtained from patients who received non-leukoreduced 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 severe cutaneous adverse reactions with allopurinol is not defined in the literature.

Rare or novel variants may be present that could lead to false-negative or false-positive results. This assay also detects closely related rare alleles including *HLA-B\*57:05*, \*58:04, \*58:05, \*58:09, \*58:10, \*58:11, \*58:12, \*58:13, \*58:15, \*58:17, \*58:19, \*58:21, \*58:22, \*58:23, \*58:24, and \*58:28. There are currently no data indicating whether these or any other alleles or subtypes are associated with allopurinol-induced severe cutaneous adverse reactions.

## **CPT Code:**

81381

**Analytic Time:** 3 days (not reported on **Day(s) Setup:** Monday through Friday Saturday or Sunday)

## **Questions:**

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