

HOTLINE: Effective February 22, 2022

3001508 *CYP2C19*

2C19GENO

Interpretive Data:

Background Information for CYP2C19:

Characteristics: The cytochrome P450 (CYP) isozyme 2C19 is involved in the metabolism of many drugs. Variants in the gene that code for CYP2C19 will influence pharmacokinetics of CYP2C19 substrates, and may predict or explain non-standard dose requirements, therapeutic failure or adverse reactions. **Inheritance:** Autosomal codominant.

Cause: CYP2C19 gene variants affect enzyme function.

Variants Tested: See the Additional Technical Information document.

Clinical Sensitivity: Drug-dependent.

Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring.

Analytical Sensitivity and Specificity: Greater than 99 percent.

Limitations: Only the targeted *CYP2C19* variants will be detected by this panel, and assumptions about phase and content are made to assign alleles. **Publicly** available sources such as the www.pharmvar.org or www.pharmgkb.org provide guidance on phenotype predictions and allele frequencies. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with CYP2C19 substrates 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.

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.

HOTLINE NOTE: There is a component change associated with this test. Add component 2008936, CYP2C19 Phenotype