

3001518

CYP3A4 and CYP3A5

3A4/3A5

Interpretive Data:**Background Information for CYP3A4 and CYP3A5:**

Characteristics: The cytochrome P450 (CYP) 3A subfamily of enzymes is involved in metabolism of many drugs. Variants in the genes that code for CYP3A4 and CYP3A5 may influence pharmacokinetics of CYP3A substrates, and may predict or explain non-standard dose requirements, therapeutic failure or adverse reactions.

Inheritance: Autosomal codominant.

Cause: CYP3A4 or CYP3A5 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 CYP3A4 and CYP3A5 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 CYP3A 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 3004504, CYP3A4 Phenotype

Add component 3004505, CYP3A5 Phenotype