HOTLINE: Effective February 22, 2022

3001524 Cytochrome P450 Genotyping Panel CYP PANEL

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring/Sequencing

Interpretive Data:

Background Information for Cytochrome P450 Genotyping Panel:

Characteristics: The cytochrome P450 (CYP) isozymes 2B6, 2C19, 2C8, 2C9, 2D6 and the CYP3A subfamily are involved in the metabolism of many drugs. Variants in the genes that code for CYP2B6, CYP2C19, CYP2C8, CYP2C9, CYP2D6, CYP3A4, and CYP3A5, and *CYP2C* cluster (rs12777823) loci, will influence pharmacokinetics of respective substrates, and may predict or explain non-standard dose requirements, therapeutic failure, or adverse reactions.

Inheritance: Autosomal codominant.

Cause: 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. Sequencing is only performed if needed to characterize a duplicated *CYP2D6* gene.

Analytical Sensitivity and Specificity: Greater than 99 percent.

Limitations: Only the targeted 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. A combination of the *CYP2D6**5 (gene deletion) and a *CYP2D6* gene duplication cannot be specifically identified; however, this combination is not expected to adversely affect the phenotype prediction. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with gene 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
Add component 3004497, CYP2C8 Phenotype
Add component 2008931, CYP2C8 Phenotype
Add component 3004499, CYP2C Cluster Genotype
Add component 3004500, CYP2C Cluster Phenotype
Add component 2008926, CYP2D6 Phenotype
Add component 3004504, CYP3A4 Phenotype
Add component 3004505, CYP3A5 Phenotype
Add component 3004493, CYP2B6 Genotype
Add component 3004494, CYP2B6 Phenotype