HOTLINE: Effective November 15, 2021

New Test **3004255** **Cytochrome P450 Genotyping Panel, with GeneDose Access** **CYP GD**

Additional Technical Information

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Varies
Reported: 5-10 days

Specimen Required: Collect: Lavender (K_2EDTA), Pink (K_2EDTA), or Yellow (ACD Solution A or B).
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin. Frozen specimens in glass collection tubes.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

Reference Interval: By report

Interpretive Data:
Background Information for Cytochrome P450 Genotyping Panel:
Characteristics: The cytochrome P450 (CYP) isozymes 2C19, 2C8, 2C9, 2D6 and the CYP3A subfamily are involved in the metabolism of many drugs. Variants in the genes that code for CYP2C19, CYP2C8, CYP2C9, CYP2D6, CYP3A4, and CYP3A5 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 expression or activity.
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 variants will be detected by this panel, and assumptions about phase and content are made to assign alleles. Publically 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.

Note: Whole blood is the preferred specimen. Saliva samples that yield inadequate DNA quality and/or quantity will be reported as inconclusive if test performance does not meet laboratory-determined criteria for reporting.

CPT Code(s): 81225; 81226; 81227; 81230; 81231; 81479

New York DOH Approved.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.