HOTLINE: Effective May 20, 2019

New Test **3001524** **Cytochrome P450 Genotyping Panel** **CYP PANEL**

Supplemental Resources

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Mon, Thu
Reported: 5-10 days

Specimen Required: Collect: **Whole Blood:** Lavender (EDTA), Pink (K_2EDTA), or Yellow (ACD Solution A or B).
Saliva: Collection Device by DNA Genotek (OCD-100, ARUP Supply #49295) available online through eSupply using ARUP Connect™ or by contacting ARUP Client Services at (800) 522-2787.
Specimen Preparation: Transport 3 mL whole blood. (Min: 1 mL) OR Transport the Saliva Collection Device.
Storage/Transport Temperature: **Whole Blood:** Refrigerated.
Saliva: Room temperature.
Unacceptable Conditions: Plasma or serum. Specimens collected in sodium heparin or lithium heparin.
Stability (collection to initiation of testing): **Whole Blood:** Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Saliva: Ambient: 2 weeks; Refrigerated: Unacceptable; Frozen: Unacceptable

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 co-dominant.
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.

See Compliance Statement C: www.aruplab.com/CS

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 approval pending. Call for status update.

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