HOTLINE: Effective February 22, 2022

**New Test** **3004310** **CYP2B6** **2B6GENO**

Additional Technical Information

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

**Specimen Required:** Collect: Lavender (EDTA), Pink ($K_2$EDTA), 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.
Stability (collection to initiation of testing): Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month

**Reference Interval:** By report

**Interpretive Data:**
**Background Information for *CYP2B6*:**
**Characteristics:** The cytochrome P450 (CYP) isozyme 2B6 is involved in the metabolism of many drugs. Variants in the gene that codes for CYP2B6 may influence pharmacokinetics of substrates and may predict or explain nonstandard dose requirements, therapeutic failure, or adverse reactions.
**Inheritance:** Autosomal codominant
**Cause:** *CYP2B6* 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 *CYP2B6* variants will be detected by this test, 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 CYP2B6 substrates may be affected by genetic and nongenetic 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 U.S. 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):** 81479

New York DOH approval pending. Call for status update.

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