HOTLINE: Effective May 20, 2019

New Test **3001508** ***CYP2C19*** **2C19GENO**

Additional Technical Information

Out of Pocket Estimator

Supplemental Resources

Methodology: Polymerase Chain Reaction/Fluorescence Monitoring
Performed: Varies
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 *CYP2C19*:
Characteristics: The cytochrome P450 (CYP) isozyme 2C19 is involved in the metabolism of many drugs. Variants in the gene that codes for CYP2C19 will influence pharmacokinetics of CYP2C19 substrates, and may predict or explain non-standard dose requirements, therapeutic failure or adverse reactions.
Inheritance: Autosomal co-dominant.
Cause: *CYP2C19* 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 *CYP2C19* 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. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with CYP2C19 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

New York DOH approval pending. Call for status update.

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