TEST CHANGE

CYP2C8, CYP2C9, and CYP2C cluster

3001501, 2C8/2C9

Specimen Requirements:	
Patient Preparation:	
Collect:	Lavender (EDTA), pPink (K2EDTA), or yYellow (ACD sSolution A or B).
Specimen Preparation:	Transport 3 mL whole blood. (Min: 1 mL)
Transport Temperature:	Refrigerated.
Unacceptable Conditions:	Plasma or serum. Specimens collected in sodium heparin or lithium heparin. Frozen specimens in glass collection tubes.
Remarks:	
Stability:	Ambient: 72 hours; Refrigerated: 1 week; Frozen: 1 month
Methodology:	Polymerase Chain Reaction (PCR)/Fluorescence Monitoring
Performed:	Varies
Reported:	5-10 days
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 Codes:	81227; 81479
New York DOH Approval Status:	This test is New York DOH approved.

Interpretive Data:

Background Information for *CYP2C8*, *CYP2C9,* and *CYP2C* cluster:
Characteristics: The cytochrome P450 (CYP) isozymes 2C8 and 2C9 are involved in the metabolism of many drugs. Variants in the genes that code for CYP2C8 and CYP2C9 may influence pharmacokinetics of substrates, and may predict or explain nonstandardnon-standard dose requirements, therapeutic failure or adverse reactions. The *CYP2C* cluster variant (rs12777823) is associated with a decreased warfarin dose requirement in some people of African descent.
Inheritance: Autosomal codominant.
Cause: *CYP2C8* and *CYP2C9* gene variants and the *CYP2C* cluster variant 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 *CYP2C8,CYP2C9*, and *CYP2C* cluster 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. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with CYP2C8 or CYP2C9 substrates may be affected by genetic and nongenetic~~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.

Reference Interval:

By report