

**TEST CHANGE** 

CYP2C8, CYP2C9, and CYP2C cluster

3001501, 2C8/2C9

Specimen Requirements:

Patient Preparation:

Collect: Lavender (EDTA), pink (K2EDTA), or yellow (ACD solution 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.

Effective Date: November 13, 2023

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:

Refer to report

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.

Couseling and informed consent are recommended for genetic testing. Consent forms are available online. 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 nonstandard 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.

Effective Date: November 13, 2023

Inheritance: Autosomal codominant.

Gause: 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 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.

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Reference Interval:

By report

HOTLINE NOTE: There is a component change associated with this test. One or more components have been added or removed. Refer to the Hotline Test Mix for interface build information.