

3001513

CYP2D6

2D6GENO

**Methodology:** Polymerase Chain Reaction/Fluorescence Monitoring/**Sequencing**

**Interpretive Data:****Background Information for CYP2D6:**

**Characteristics:** The cytochrome P450 (CYP) isozyme 2D6 is involved in the metabolism of many drugs. Variants in the gene that code for CYP2D6 may influence pharmacokinetics of CYP2D6 substrates, and may predict or explain non-standard dose requirement, therapeutic failure or adverse reactions.

**Inheritance:** Autosomal codominant.

**Cause:** CYP2D6 gene variants and copy number affect enzyme **function**.

**Variants Tested:** See the "Additional Technical Information" document.

**Clinical Sensitivity:** Drug-dependent.

**Methodology:** Polymerase chain reaction (PCR) and fluorescence monitoring. **Sequencing is only performed if needed to characterize a duplicated CYP2D6 gene.**

**Analytical Sensitivity and Specificity:** Greater than 99 percent.

**Limitations:** Only the targeted CYP2D6 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](http://www.pharmvar.org) or [www.pharmgkb.org](http://www.pharmgkb.org) provide guidance on phenotype predictions and allele frequencies. A combination of the \*5 (gene deletion) and a gene duplication cannot be specifically identified. 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 CYP2D6 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.

**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.

**HOTLINE NOTE:** There is a component change associated with this test.

Add component 2008926, CYP2D6 Phenotype