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# DNA DRUG SENSITIVITY TEST (DST) RESULTS
## Cytochrome P450 CYP2C19 Test

Genelex Laboratory # **CRM 13XXX** Report Date: 10/20/09

**Patient Name:** **John Doe** Collection Date: 10/15/09

Date of Birth: April 12, 1952 Sample Type: Buccal Receipt Date: 10/16/09

**Cytochrome P450 CYP2C19 Genotype (Phenotype) Interpretation:** **DST CYP2C19 *1/*3 Intermediate Metabolizer**

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**Laboratory Test Interpretive Comments:**

**Normal metabolizers** represent the norm for metabolic capacity. In general normal metabolizers can be administered drugs which are substrates of the CYP2C19 enzyme following standard dosing practices. Genotypes consistent with the normal metabolizer phenotype include two active CYP2C19 alleles.

**Intermediate metabolizers** may require lower than average drug dose for optimal therapeutic response to medications with the exception of prodrugs. For the majority of drugs consider decreased dosage. For prodrugs, like Plavix, that require activation by CYP2C19, an alternative treatment or increased dose should be considered. Genotypes consistent with the intermediate metabolizer phenotype are those with one active and one inactive CYP2C19 allele.

**Poor metabolizers** are at increased risk of drug-induced side effects due to diminished drug elimination or for prodrugs, like Plavix, lack of therapeutic effect resulting from failure to generate the active form of the drug. Alternative treatment should be considered. Genotypes consistent with the poor metabolizer phenotype are those with no active CYP2C19 alleles.

**Co-administration of other drugs**. Genotype results should be interpreted in context of the individual clinical situation including co-administration of other drugs, hepatic and renal function. Genotype results should be interpreted in context of the individual clinical situation. In all cases monitor for co-administration of CYP2C19 inhibitors which may convert patients to poor metabolizer status. Potential adverse outcomes included overdose toxicity or treatment failure particularly for prodrugs. For more information see GeneMedRx drug-drug and drug-gene interaction software and Cytochrome P450 Metabolism Inhibitor/Inducer Tables. Access GeneMedRx via the patient access code provided at www.GeneMedRx.com/DNAlogin.

**DNA Drug Sensitivity Test (DST) Cytochrome P450 CYP2C19 alleles tested:**

Active allele: CYP2C19 *1
Inactive alleles: CYP2C19 *2 or *3 or *4 or *5 or *6 or *7 or *8
Analytical specificity and sensitivity for detection of these mutations are >99%. Other known variants not listed are not detected.
*Note: This is a list of all tested markers and is no indication of your genetic profile. Your genotype is in the box above.*

**Clinical Indication for Testing:**

For individuals with a personal or family history of adverse drug reactions to medications metabolized by CYP2C19. Confirm presence of genotypes that affect metabolism of Plavix (clopidogrel) or any drugs that are metabolized by cytochrome CYP2C19.



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**Methodology:**

This assay detects all common and most rare CYP2C19 variants with known clinical significance. Laboratory specimens were analyzed using the xTAG™ Mutation Detection system for P450-2C19 (Luminex Molecular Diagnostics) which detects 7 nucleotide variants in a multiplex polymerase chain reaction and allele-specific primer extension format. The performance of the xTAG™ Mutation Detection system for P450-2C19 for use with the Luminex 100 xMAP IS System was validated by Genelex Corporation. Rare CYP2C19 variants may not yet have been observed at Genelex. This test does not detect polymorphisms other than those listed. Other polymorphisms in the primer binding regions can affect the testing, and ultimately, the genotyping assessments made. Rare diagnostic errors may occur due to primer site mutations. Drug metabolism may be affected by non-genetic factors. DNA testing does not replace the need for clinical and therapeutic drug monitoring. As with all laboratory testing there is a possibility of error. Genelex Corporation is certified by the Clinical Laboratory Improvement Amendments (CLIA No. 50D0980559) and as Washington State Medical Test Site No. MTS-39190 is qualified to perform high complexity clinical testing. Genetic counseling is recommended.

**References:**

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