CYP2C19 Genotype

CPT Code: 81225
Order Code: 1086
ABN Requirement: No
Synonyms: Cytochrome P450 2C19
Specimen: EDTA Whole Blood
Volume: 4.0 mL
Minimum Volume: 2.0 mL
Container: EDTA (Lavender Top) tube

Collection:

1. Collect and label sample according to standard protocols.
2. Gently invert tube 10 times immediately after draw. Do not shake.
3. Do not centrifuge.

Please Note: This germline genetic test requires physician attestation that patient consent has been received if ordering medical facility is located in AK, DE, FL, GA, IA, MA, MN, NV, NJ, NY, OR, SD, or VT or test is performed in MA.

Special Instructions: A separate EDTA whole blood tube is needed for molecular tests. Collect additional samples for other testing that requires EDTA whole blood. Multiple (up to 8) cardiovascular-related genetic tests can be performed on a single specimen. A second lavender-top (EDTA) tube is required if non-genetic tests are simultaneously ordered that require a lavender top (EDTA) tube. For whole blood samples, follow normal phlebotomy procedures.

Transport: Store EDTA whole blood at 2°C to 8°C after collection and ship the same day per packaging instructions included with the provided shipping box.

Stability:

Ambient (15-25°C): 8 days
Refrigerated (2-8°C): 8 days
Frozen (-20°C): 30 days

Causes for Rejection: Specimens other than EDTA whole blood; improper labeling; samples not stored properly; samples older than stability limits

Methodology: Allele-Specific Primer Extension, Polymerase Chain Reaction (PCR)

Turn Around Time: 4 to 7 days

Relative Range: See Laboratory Report

Clinical Significance: This pharmacogenetic test may be used to help guide clopidogrel prescribing, especially in patients with acute coronary syndrome (ACS) who have undergone percutaneous coronary intervention (PCI) [1]. This test detects common variants in the CYP2C19 gene, the most validated genetic determinant of clopidogrel response.

Clopidogrel is a prodrug that needs to be metabolized to its active form by cytochrome P450 2C19 (CYP2C19). Patients who carry a no-function allele of CYP2C19 have reduced clopidogrel activation, reduced platelet inhibition, and higher risk of major adverse cardiovascular events. Treatment outcomes may be improved in these patients with alternative antiplatelet therapies, such as prasugrel or ticagrelor. Therefore, CYP2C19 genotyping is helpful for assessing an individual's capability to metabolize clopidogrel and optimizing antiplatelet therapy [1].

CYP2C19 genotype classifies individuals as ultrarapid, rapid, normal, intermediate, likely poor, poor, and indeterminate metabolizers. The Clinical Pharmacogenetics Implementation Consortium (CPIC) provides guidelines for using CYP2C19 status to help direct clopidogrel prescribing. Although the association between CYP2C19 genotype and clopidogrel response is most established in patients with ACS who have undergone PCI, growing evidence indicates a similar association in patients with neurovascular indications [1]. The FDA boxed warning indicates diminished antiplatelet effect in CYP2C19 poor metabolizers and availability of tests to identify these individuals [2].

This is a targeted genotyping test and does not detect deletions or novel or rare variants of CYP2C19. CYP2C19 genotype does not identify all the variability in clopidogrel response. Other factors, such as age, body mass index, chronic kidney disease, diabetes mellitus, and concomitant use of certain proton pump inhibitors, may also influence clopidogrel response [1].

The results of this test should be interpreted in the context of pertinent clinical

and family history and physical examination findings.
Additional assistance in test selection and interpretation of results is available from our genomic science specialists by calling 1.866.GENE.INFO (1.866.436.3463).

References:

1. Lee CR, et al. Clin Pharmacol Ther. 2022;10.1002/cpt.2526.
2. PLAVIX(R) (clopidogrel bisulfate). Prescribing information. Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership; 2019. Accessed March 5, 2022. https://packageinserts.bms.com/pi/pi_plavix.pdf

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