

Cytochrome P450 2C19 (CYP2C19) Genotyping

Disease Overview

CYP2C19, an enzyme in the cytochrome P450 (CYP) family, is responsible for the metabolism of many commonly prescribed medications. Medications with dosing guidance based on *CYP2C19* information can be found on the Clinical Pharmacogenetics Implementation Consortium website at: <https://cpicpgx.org/guidelines/>

Uses for Test

- To estimate genetic risk of abnormal drug metabolism for drugs metabolized by *CYP2C19*.
- To identify genotypes shown to have a drug-gene variant relationship.
- Pharmacogenomic orders may be reviewed by a pharmacist for clinical appropriateness prior to test completion if clinical data is available.

Therapeutic Implications

Cytochrome P450 2C19 (*CYP2C19*), is involved in the metabolism of many commonly used drugs. Impaired drug metabolism may cause adverse drug reactions or may lead to a lack of drug response at a standard dose.

Treatment Guidelines

- The Clinical Pharmacogenetics Implementation Consortium (CPIC) has published dosing guidelines for *CYP2C19* genotypes: <https://cpicpgx.org/>

Test Interpretation

- Clinical sensitivity: drug dependent
- Analytical sensitivity/specificity: > 99%

Results

A detailed report is provided. This report is reviewed and signed out by a Laboratory Director. No mutations detected is predictive for *1 functional alleles.

Test Limitations

- Only the targeted *CYP2C19* variants will be detected.
- Diagnostic errors can occur due to rare sequence variations.
- Risk of therapeutic failure or adverse reactions with *CYP2C19* 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 evaluation and monitoring.

Related Tests

- Multiple genes can be involved in drug metabolism, drug activation and drug action on the target tissue. Additional genotyping tests are available for *CYP2D6*, *CYP2C9*, *VKORC1*, *SLCO1B1*, *TPMT*, *CYP3A5*, *IFNL3*, *CYP4F2*, *CYP2C cluster* and *DPYD* as individual tests or as a PGx Panel.
- The panel includes a comprehensive medication report based on the genotypes detected
- Therapeutic drug monitoring and/or metabolic ratios may be useful for evaluating the pharmacokinetics of a particular drug, for a particular patient.

Sample Requirements

• Collection

- Lavender-top tube (EDTA)
- All specimens should be sent in the original container and should not be aliquoted to another tube.
- The specimen submitted should only be used for this testing and should not be shared with any other testing that would also utilize this specimen type.

• Specimen

- Whole Blood, preferred Volume: 2 mL to 4 mL (1mL minimum)

• Stability

- Room temp – 72 hours
- Refrigerated – 7 days
- Frozen – 7 days
- Not affected by hemolysis
- Not affected by lipemia

Test Involved

- CPT code: 81225
- Lab Test ID: LBOR0140

Test Schedule

- Set up Monday to Friday
- Turn Around Time: 5-7 days

Additional information

- These tests are available through the Sanford Imagenetics program. Contact Sanford Laboratories at (605) 328-5464 or (800) 522-2561 for questions regarding this testing.

Rev. 4/2021

References

• Beverage JN, Sissung TM, Sion AM, et al. CYP2D6 polymorphisms and the impact on tamoxifen therapy. *J Pharm Sci* 96:2224-2231, 2007. • SA Scott, K Sangkuhl, CM Stein, J-S Hulot, JL Mega, DM Roden, TE Klein, MS Sabatine, JA Johnson and AR Shuldiner : Clinical Pharmacogenetics Implementation Consortium Guidelines for CYP2C19 Genotype and Clopidogrel Therapy: 2013 Update • Mega, J.L. et al. Cytochrome p-450 polymorphisms and response to clopidogrel. *N. Engl. J. Med.* 360, 354–362 (2009). • Charles M. Strom MD, PhD, Dana Goos BS, Beryl Crossley MD, Ke Zhang PhD, Arlene Buller-Burkle PhD, Michael Jarvis PhD, Franklin Quan PhD, Mei Peng PhD & Weimin Sun PhD : Testing for variants in CYP2C19: population frequencies and testing experience in a clinical laboratory • Clinical Pharmacogenetics Implementation Consortium guidelines for CYP2C19 genotype and clopidogrel therapy: 2013 update, the 2013 supplement and other relevant resources at www.pharmgkb.org • Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline for CYP2D6 and CYP2C19 genotypes and dosing of selective serotonin reuptake inhibitors, available along with the 2015 supplement and other relevant resources at www.pharmgkb.org • Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline for CYP2D6 and CYP2C19 genotypes and dosing of tricyclic antidepressants, available along with the 2013 supplement and other relevant resources at www.pharmgkb.org • The human cytochrome P450 (CYP) allele nomenclature database, available at www.cypalleles.ki.se/ • Plavix® (clopidogrel bisulfate) prescribing information. Available at <http://products.sanofi.us/plavix/plavix.pdf> <https://cpicpgx.org/guidelines/>

SANFORD
Laboratories

SANFORDHEALTH.ORG/IMAGENETICS