Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003827 M 07/08/1978 45 Y

Referral Testing

Collected: 07/18/2023 10:23 Received: 07/18/2023 10:23

Test Name	Result	Flag	Ref-Ranges	Units	Site
Accutype Cp, Clopidogrel	See Below				QCRL

RESULT: INTERMEDIATE METABOLIZER (CYP2C19*1/CYP2C19*2)

DNA testing indicates this individual has one copy of the CYP2C19*2 no function or decreased function CYP2C19 allele and is negative for the other alleles in the CYP2C19 gene examined. This genotype result predicts an intermediate metabolizer phenotype, which translates to reduced CYP2C19 function. This patient is expected to have reduced response to clopidogrel. Intermediate metabolizers may require alternative treatments or altered drug dosage of a drug metabolized by CYP2C19 for optimal therapeutic response, as clinically indicated.

Laboratory results reviewed and released by qualified personnel.

The cytochrome P450 2C19 (CYP2C19) gene (NM 000769.1) codes for the CYP2C19 enzyme. This enzyme is primarily found in the liver and is involved in the metabolism of a number of clinically important drugs. The clinical impact of the CYP2C19 genotype on the metabolism of specific drugs will vary based on non-genetic factors, such as hepatic and renal status, other medications used (including over-the-counter medications, herbals and other supplements), alcohol or illegal drug use, race, age, weight, diet, and diseases present in an individual patient. Detection of genetic variants does not replace the need for drug and clinical monitoring.

Many medications serve as substrates, inhibitors, or inducers of the CYP2C19 enzyme, including some proton pump inhibitors, antidepressants, antimicrobials and anti-seizure medications. Co-administration of CYP2C19 inhibitors may convert patients to poor metabolizer status. Consultation with a clinical pharmacy professional to discuss drug and dose selection may be helpful in understanding the implications of these test results and management options.

The normal (wild-type) CYP2C19 allele is designated as CYP2C19*1. This assay detects 10 common alleles in the CYP2C19 gene which are associated with altered CYP2C19 enzyme activity. These include seven no function alleles (CYP2C19*2 (19154G>A, rs4244285, c.681G>A), CYP2C19*3 (17948G>A, rs4986893,c.636G>A), CYP2C19*4 (rs28399504, c.1A>G), CYP2C19*5 (90033C>T, rs56337013, c.1297C>T), CYP2C19*6 (12748 G>A, rs72552267,c.395G>A), CYP2C19*7 (19294T>A, rs72558186, c.819+2T>A), CYP2C19*8 (12711T>C, rs41291556, c.358T>C)), two decreased function alleles CYP2C19*9 (12784G>A, rs17884712, c.431G>A) and CYP2C19*10 (19153C>T, rs6413438; c.680C>T), and the CYP2C19*17

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(rs12248560, c.-806C>T) allele which is associated with increased CYP2C19 activity. The CYP2C19 variants described above are detected by single nucleotide primer extension after multiplex-polymerase chain reaction (PCR) amplification of specific regions of the CYP2C19 gene. Fluorescent extension products are analyzed on an automated, capillary DNA sequencer.

The alleles tested for by this assay account for more than 99% of CYP2C19 poor metabolizers in Asian populations and approximately 90% in Caucasians. Three to five percent of Caucasians and 13-23% of Asians carry two CYP2C19 no function alleles and have the poor metabolizer phenotype for clopidogrel and other CYP2C19 substrates. Additional information regarding the significance of gene-drug interactions can be found in a number of places, including the package insert, FDA websites, the clinical pharmacogenetics implementation consortium (CPIC), as well as PharmGKB (http://www.pharmgkb.org) and the primary literature. It is important to keep in mind that certain medications may be inhibitors of CYP2C19 and lead to drug-drug interactions.

Although rare, false positive or false negative results may occur. All results should be interpreted in context of clinical findings, relevant history, and other laboratory data. For questions regarding this test please call 866-436-3463 (866 GENE INFO).

This test is performed pursuant to a license agreement with Orchid Biosciences, Inc.
This test was developed and its analytical performance characteristics have been determined by Quest Diagnostics Nichols Institute San Juan Capistrano. It has not been cleared or approved by FDA. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes.
Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA

Performing Site:
QCRL: QUEST DIAGNOSTICS REFERENCE LAB CAPISTRANO 33608 Ortega Highway San Juan Capistrano CA 92675

Reported Date: 2023.07.18 10:24