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: 09/25/2023 09:47 Received: 09/25/2023 09:47

Test Name	Result	Flag	Ref-Ranges	Units	Site
Cytochrome P450 2d6 Genotype	See Below				QCRL

RESULT: HETEROZYGOUS POSITIVE FOR THE CYP2D6*5 NO FUNCTION ALLELE

INTERPRETATION: DNA analysis indicates that this individual is positive for one copy of the CYP2D6*5 no function allele. This individual is negative for a duplication of the CYP2D6 gene (genotype CYP2D6*1/CYP2D6*5).

This individual is predicted to have the Intermediate Metabolizer phenotype. The reduction in CYP2D6 activity may be significant enough to reduce the therapeutic efficacy of some drugs that require CYP2D6 activity for the generation of the active metabolite(s). In addition, there may be an increased risk for toxicity or adverse side effects if this individual is administered drugs that are inactivated by CYP2D6.

This individual may be positive for a rare CYP2D6 variant that is not tested for by this assay. Genetic counseling is recommended.

Laboratory testing supervised and results monitored by

Cytochrome P450 2D6 (CYP2D6) is an enzyme that is responsible for the metabolism of a wide variety of compounds (e.g., >25% of available medications) including antidepressants, antipsychotics, codeine, tamoxifen and many others. Both genetic and environmental factors can influence the level of CYP2D6 activity. Variations in the CYP2D6 gene (i.e., allelic differences) can contribute to inter-individual differences in enzyme levels and/or activity, and therefore, inter-individual variations in the efficacy and/or toxicity of various compounds. In some cases, medication response may be impacted by variants in other genes and additional genetic testing could provide additional insights.

The normal CYP2D6 allele is designated as CYP2D6*1. This assay detects 7 no function alleles: CYP2D6*3 (c.775delA, rs35742686), CYP2D6*4 (c.506-1G>A, rs3892097), CYP2D6*5 (gene deletion), CYP2D6*6 (c.454delT, rs5030655), CYP2D6*7 (c.971A>C, rs5030867), CYP2D6*8 (c.505G>T, rs5030865), and CYP2D6*14A (CYP2D6*114) (c.505G>A, rs5030865 and c.100C>T, rs1065852). It also detects 5 decreased function alleles: CYP2D6*9 (c.841_843delAAG, rs5030656), CYP2D6*10 (c.100C>T, rs1065852), CYP2D6*14B (CYP2D6*14) (c.505G>A, rs5030865), CYP2D6*17 (c.320C>T, rs28371706), and CYP2D6*41 (c.985+39G>A, rs28371725). Duplications of the CYP2D6 gene are detected, but this assay cannot determine the identity of the duplicated allele(s) nor can it determine the precise number of copies of the CYP2D6 gene. An allele that is negative for the variants tested for by this assay is

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inferred to be the CYP2D6*1 (normal) allele.

The predicted CYP2D6 phenotype is based on the Clinical Pharmacogenomics Implementation Consortium (CPIC) activity scoring system (0 = Poor Metabolizer, 0.25-1 = Intermediate Metabolizer, 1.25 to 2.25 = Normal Metabolizer, >2.25 = Ultrarapid Metabolizer). Approximately 3% of African Americans, 6% of Caucasians, and 1% of East Asians are predicted to be Poor Metabolizers.

Variants in the CYP2D6 gene are detected by single nucleotide primer extension after polymerase chain reaction (PCR) amplification of the CYP2D6 gene. Fluorescent extension products are analyzed by capillary electrophoresis. This test cannot rule out the presence of variants in other regions of the CYP2D6 gene.

Although rare, false positive or false negative results may occur. All results should be interpreted in the context of clinical findings, relevant history, and other laboratory data.

Additional information can be found by consulting PharmGKB (www.pharmgkb.org), CPIC (cpicpgx.org), and www.fda.gov/drugs/science-research-drugs/table-pharmacogenomic-biomarkers-drug-labeling. Health care providers may also contact your local Quest Diagnostics' genetic counselor or call 1-866-GENEINFO (866-436-3463) for assistance with the interpretation of these results.

This test is performed pursuant to license agreements with Orchid Biosciences.

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 the FDA. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes.
Reviewed and signed by Laboratory testing supervised and results monitored by
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: 2023.09.25 9:47