Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003826 F 12/05/1988 34 Y

Referral Testing

Collected: 08/18/2023 10:47 Received: 08/18/2023 10:47

Test Name	Result	Flag	Ref-Ranges	Units	Site
Warfarin Accutype	See Below				QCRL

VKORC1: NEGATIVE FOR THE -1639G>A VARIANT (Genotype GG)
VKORC1: NEGATIVE FOR p.D36Y AND p.V66M
CYP2C9: INTERMEDIATE METABOLIZER (IM) (Genotype*1/*2)

VKORC1: DNA testing indicates this individual carries two copies (homozygous) of the -1639G normal allele of the VKORC1 gene and does not have an increased risk of warfarin sensitivity due to the -1639G>A nucleotide change. However, this test cannot rule out the possibility that he or she is a carrier of other rare mutations causing higher sensitivity to the anticoagulation effect of the warfarin therapy.

VKORC1 VARIANTS: DNA testing indicates that this individual is negative for the p.D36Y and p.V66M warfarin resistance variants. This test cannot rule out the possibility that he/she is a positive for a warfarin resistance variant that is not detected by this assay.

CYP2C9: DNA testing indicates this individual has one copy of the *2 allele and is negative for the other tested variants in the CYP2C9 gene. The predicted genotype is CYP2C9*1/*2. An individual with one copy of the *2 allele is expected to have lower CYP2C9 enzyme activity (levels between normal and poor metabolizer). This test cannot rule out the possibility of a rare variant not tested for by this assay which could result in a poor metabolizer (PM) phenotype.

To calculate the appropriate warfarin dosage, please go to http://www.warfarindosing.org and submit the patient's genotypic and demographic data.

Laboratory results and submitted clinical information reviewed by Guity Ghaffari, Ph.D., FACMG, HCLD, CGMB.

Warfarin (coumadin) therapy is associated with significant complications because of its narrow therapeutic index, and the large inter-patient variation in dosage required for an optimal therapeutic response. This variation is due to both genetic and environmental factors. Genetic factors include variants of the Vitamin K Epoxide Reductase Complex subunit 1 (VKORC1) and Cytochrome P450 2C9 (CYP2C9) genes, which account for approximately 25%-44% and 10%-15% of the variability respectively. Identification of these VKORC1 and CYP2C9

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003826 F 12/05/1988 34 Y

Referral Testing

Collected: 08/18/2023 10:47 Received: 08/18/2023 10:47

Test Name	Result	Flag	Ref-Ranges	Units	Site

variants could allow a more individualized course of therapy, and reduce the risk of bleeding or thrombotic complications.

This assay detects variants from two genes, VKORC1 and CYP2C9. The variants detected by this assay are: the common warfarin sensitive polymorphism, -1639 G>A, and warfarin resistance polymorphisms, D36Y and V66M, of the VKORC1 gene and the four common poor metabolizer genetic variants of the CYP2C9 gene: CYP2C9*2 (R144C), CYP2C9*3 (I359L), CYP2C9*5 (D360E) and CYP2C9*6 (818delA), as well as the wild type allele (CYP2C9*1). Approximately 42%-46% of Caucasians, 13% of African-Americans and 90%-95% of Asians carry at least one copy of the -1639A VKORC1 variant allele. Approximately 4% of the Ashkenazi Jewish individuals carry the D36Y warfarin resistance allele. Approximately 33% of Caucasians, 3%-13% of Africans, and 2%-8% of Asians are positive for at least one of the CYP2C9 poor metabolizer variant alleles.

The VKORC1 and CYP2C9 variants described above are detected by polymerase chain reaction (PCR) amplification of the appropriate regions of the VKORC1 (promoter exons 1 and 2) and CYP2C9 (exons 3, 5, and 7) genes, followed by a single nucleotide primer extension reaction and detection of fluorescent extension products on an automated DNA sequencer.

DNA-based testing is highly accurate, but rare false negative/false positive results may occur. Please contact the laboratory if you have questions about these test results. Since genetic variation and other problems can affect the accuracy of direct mutation testing, test results should always be interpreted in light of clinical and familial data.

For assistance with the interpretation of these results, please contact your local Quest Diagnostics Genetic Counselor or call 1-866-GENEINFO (1-866-436-3463).

This test was 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.
Reviewed and signed by Laboratory results and submitted clinical information reviewed by Guity Ghaffari, Ph.D., FACMG, HCLD, CGMB,
Signed on 05/19/2023 at 01:17
Test Performed at:
Quest Diagnostics Nichols Institute

Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003826 F 12/05/1988 34 Y

Referral Testing

Collected: 08/18/2023 10:47 Received: 08/18/2023 10:47

Test Name	Result	Flag	Ref-Ranges	Units	Site
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: 2023.08.18 10:48

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

F218000038
WX0000003826
Printed D&T: 08/18/23 10:48

Ordered By: KAJAL SITWALA, MD, PhD
WX00000000002353

Kajal V. Sitwala, MD, PhD - Medical Director
Form: MM RL1