Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT
WX0000003039 M 12/05/1988 33 Y

Molecular

Collected: 02/19/2022 06:06 Received: 02/19/2022 06:06

Test Name	Result	Flag	Ref-Ranges	Units	Site

Factor V Leiden Mutation Analysis

Factor V Leiden Mutation	**Heterozygous**	**AB**	WMRL

Both the wild type (WT) F5 gene and the pathogenic F5 Leiden variant (c.1691G>A) were detected indicating a heterozygous c.1691G>A genotype for this specimen. Heterozygosity for the c.1691G>A variant is associated with activated protein C resistance and an increased risk for venous thromboembolism (VTE).

Factor V Leiden thrombophilia is inherited in an autosomal dominant manner and adults heterozygous for the F5 Leiden variant have a 3 to 8-fold increased risk of VTE. The prevalence of c.1691G>A heterozygosity is highest in individuals of European ancestry (5.2%). The variant is less common in Americans with Hispanic (2.2%), African (1.2%), Asian (<0.5%), and Native American (1.25%) ancestry. The overall risk of a first VTE in heterozygous individuals is approximately 0.5%. Patients heterozygous for both F5 Leiden and the G20210A (c.*97G>A) prothrombin variant may experience earlier onset of thrombosis that tends to be more severe than individual alleles. Genetic counseling is recommended to help determine the benefit of testing asymptomatic family members.

This test was performed using the cobas® Factor V Test (Roche) - an in vitro diagnostic device that uses real-time quantitative Polymerase Chain Reaction (qPCR) for the detection and genotyping of the human factor V (F5) gene. The test detects the presence of the wild type (WT) F5 gene and the pathogenic c.1691G>A variant (also known as the F5 Leiden variant) in genomic DNA isolated from whole blood specimens as an aid in diagnosing patients with suspected thrombophilia. The cobas® Factor V Test and the cobas z 480 analyzer are used together for automated amplification and detection. The limit of detection for this test is 0.1 ng/uL of genomic DNA (2.5 ng/PCR reaction).

Performing Site:
WMRL: WARDE MEDICAL LABORATORY 300 West Textile Road Ann Arbor MI 48108

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