

# FDA/510(k) Approved eQ-PCR™ LC Warfarin Genotyping Kit



## A Simple, Closed-Tube Walk-Away Real-Time PCR

The single nucleotide polymorphisms (SNPs) in CYP 2C9 gene of the cytochrome P450 enzyme and the VKORC1 (vitamin K epoxide reductase complex subunit 1) gene have been shown to contribute to inter-individual variability of the warfarin response. These SNPs can serve as genetic markers for warfarin dosage prediction in clinical practice.

The LightCycler Warfarin test is designed for genotyping the SNPs in the 2C9\*2 (C430T), 2C9\*3 (A1075C) and VKORC1 (-1639 G>A) genes. The test can use DNA from whole blood or non-invasive buccal swab\*. Detection is performed using the Roche LightCycler® v.1.2 Real-Time PCR System.

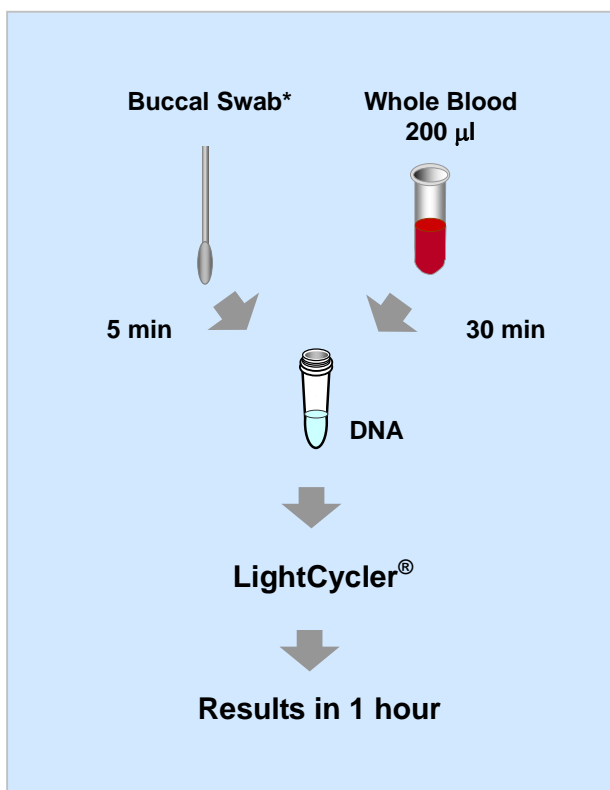
### Exclude False Results from Pseudo Genes

Cytochrome P450 (CYP) 2C9 gene contains highly conserved sequences shared by several pseudo genes. The eQ-PCR™ LC Warfarin genotyping test selectively detects for the SNPs in the 2C9 gene to provide accurate results.

### Uses Buccal Swab\* Sample

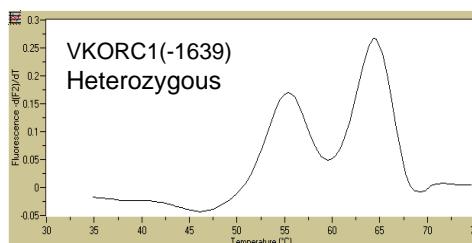
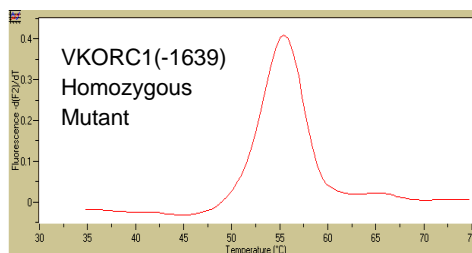
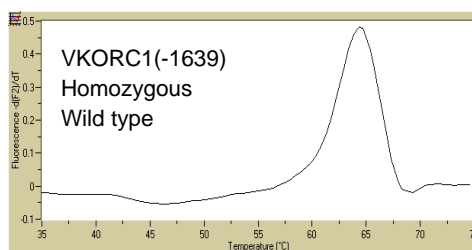
The sample collection can be performed at home or in clinics using TrimGen's Easy-Swab. The DNA in the swab is stable at room temperature for up to 6 months. The buccal DNA can be extracted in 5 minutes using TrimGen's BuccalQuick™ kit.

## Test Overview

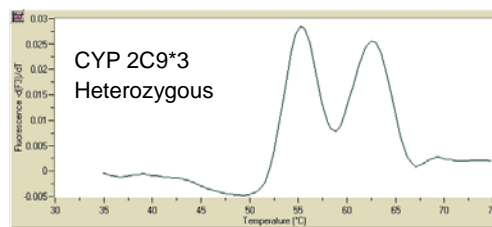
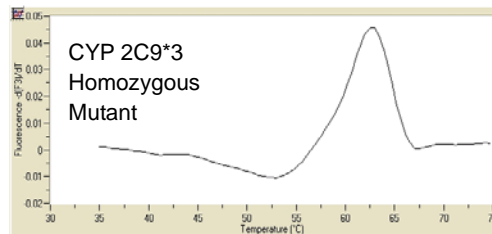
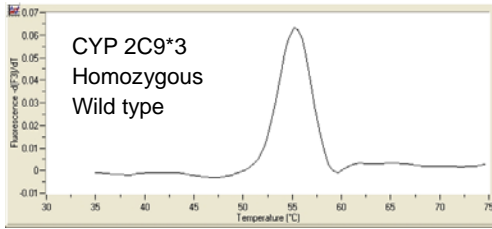


\*Buccal Swab application has yet to be FDA approved.

## Test Results-VKORC1 (-1639)



### Test Results-CYP 2C9 \*3

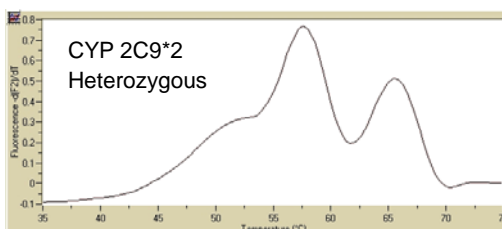
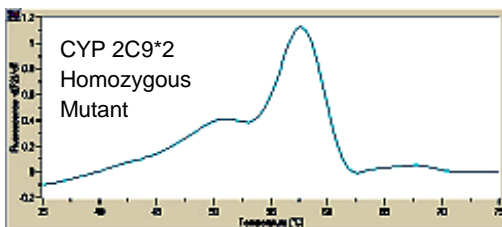
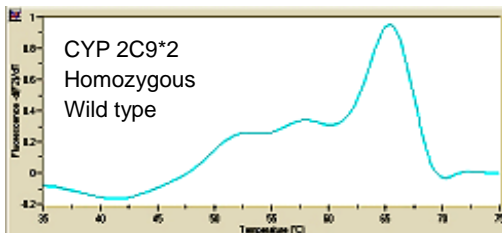


### Real-time PCR Test

The eQ-PCR™ LC Warfarin Genotyping Kit uses real-time PCR to amplify the target genes and the SNP genotype is determined by melting curve analysis. The PCR design selectively amplifies the 2C9 gene from a group of pseudo genes to achieve an accurate detection. The whole assay takes less than 2 hours and is easy to use. The performance of the kit is stable with reliable and highly reproducible results.

TrimGen has completed a clinical trial for the eQ-PCR™ LC Warfarin Genotyping kit and has received FDA/510(k) clearance. The trial performed over 5000 tests in three trial sites and the results showed 100% correlation with the results from bi-directional sequencing.

### Test Results-CYP 2C9 \*2



### Test Information

#### Test equipment:

LightCycler V1.2

#### Sample:

Whole blood 200 μl  
Buccal cells (Easy-Swab, TrimGen)

#### Test time (include DNA extraction):

2 hours for whole blood  
1.5 hours for buccal swab



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