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Carefully read the instructions on the labeling and/or in the user manual.

ThromboGUARD FII FV

Multiplex detection kit
for thrombophilia FII / FV by real-time PCR



Standardised

Result interpretation by scatter plot analysis



Multiplex

Simultaneous analysis of two major thrombophilic mutations in a single reaction



Reliable

Qualitative detection of Factor II (G20210A) and Factor V Leiden (G1691A) mutations

For professional use only.
HLAB27 GUARD is a Class C in vitro diagnostic medical device in compliance with Regulation (EU) 2017/746.

Ref. :
GED/D000845
V2EN 20-01-2026

ThromboGUARD FII FV

Multiplex detection kit
for thrombophilia FII / FV by real-time PCR

DESCRIPTION

Hereditary thrombophilia linked to mutation of Factor II (FII) or Factor V Leiden (FV) is a genetic disorder affecting proteins of the coagulation system. Mutations of Factor II and Factor V Leiden are present in approximately 2% and 5% of the general Caucasian population respectively.

ThromboGUARD FII FV is a multiplex real-time PCR detection kit enabling qualitative identification of major thrombophilic mutations FII G20210A and FV Leiden G1691A. The analysis is based on a specific amplification followed by allelic discrimination through fluorimetric reading and graphical representation in the form of scatter plots, facilitating genotype interpretation.

The solution is designed for simple and standardised use in routine molecular biology, with a ready-to-use master-mix and integrated controls allowing full validation of each analytical run.

Validated sample

- Whole blood collected in EDTA tube

Target sequences

- Factor II G20210A (gene)
- Factor V Leiden G1691A (gene)

Validated instruments

- Extracteur QIA Symphony® SP (QIAGEN)
- CFX96™ Real-Time PCR Detection System (Bio-Rad), associated with Bio-Rad CFX Maestro Dx SE.

The example shown illustrates results obtained with Bio-Rad CFX Maestro software for controls and NTC (molecular biology grade water), in configuration Factor V – ROX / Cy5.

- Circle / orange: Allele 1 – wild-type homozygous
- Triangle / green: Heterozygous
- Square / blue: Allele 2 – mutant homozygous
- Diamond / black: NTC point (PCR negative control)

Ease of use

- Ready-to-use master-mix
- Complete kit including :
 - . Master-mix
 - . Mutant homozygous control
 - . Wild-type homozygous control
 - . Heterozygous control

Performances

The ThromboGUARD FII FV kit has undergone a complete performance validation, including both analytical and clinical performance.

Alleles	Lower limit of detection	Specificity*	Sensitivity*
Facteur II	0,65 ng/μL	100 %	100 %
Facteur V	0,65 ng/μL	100 %	100 %

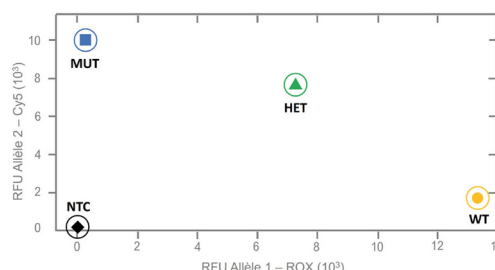
* Diagnostic specificity and sensitivity within the framework of clinical performances.

Result analysis

Result interpretation is performed using Bio-Rad CFX Maestro Dx software for controls and clinical samples, according to scatter plot graphical representation :

- Circle / orange: Allele 1 – wild-type homozygous
- Triangle / green: Heterozygous
- Square / blue: Allele 2 – mutant homozygous
- Diamond / black: NTC point (PCR negative control)

This visual approach enables rapid, reliable and reproducible reading of genotypic profiles.



Orders

Tel. : +33 (0)4 37 57 00 54

E-mail : commandes@appolonbiotech.com

APPOLON BIOTECK

205 rue des frères Lumière
69970 Chaponnay
FRANCE



205 rue des frères Lumière
ZAC du Chapotin
69970 Chaponnay
FRANCE

+33 (0)4 37 57 00 54
contact@appolonbiotech.com

