# FV LEIDEN G1691A POLYMORPHISM

For in vitro diagnostic use

CE IVD

## ORDERING INFORMATIONS

*REF: GEN-001-25 RDM Code: 1718429/R*
*Tests: 25 Reactions: 31*
*REF: GEN-001-50 RDM Code: 2255477/R*
*Tests: 50 Reactions: 62*
*CND Code: W0106010103*
*Manufacturer: BioMol Laboratories s.r.l.*

## CONTENTS OF THE KIT

*The kit consists of: reagents for Real-Time PCR amplification*
**reagents for the extraction of genomic DNA are not supplied in the kit*

## PRODUCT CHARACTERISTICS

Determination of the G1691A FV Leiden polymorphism by Real-Time PCR technique. Optimized kit for Real-Time PCR instrumentation Biorad CFX96 Dx, Biorad Opus Dx, Agilent AriaDx, Hyris bCUBE and Hyris bCUBE3 with Hyris bAPP.

## SCIENTIFIC BACKGROUND

Venous thromboembolism (VTE), usually involving deep vein thrombosis, pulmonary embolism, or both, is a complex, multifactorial disorder in which a number of conditions interact and contribute to increased individual risk culminating in the development of venous occlusives. Thrombophilia is commonly defined as a propensity to develop venous thromboembolism based on a hypercoagulable condition attributable to inherited or acquired disorders involving blood clotting or fibrinolysis.

Among the environmental risk factors, some can lead to increased hypercoagulability, for example cancer, surgery, trauma or fracture, immobilisation, pregnancy and the postpartum period, long-distance travel, hospitalization, catheterization and acute infection and others may be considered as predisposing conditions, such as age, gender, race/ethnicity, body mass index and obesity, use of oral contraceptive or hormone therapy, corticosteroids or statins, diet, physical activity, sedentary weather and air pollution.

## CLINICAL SIGNIFICANCE

Venous thromboembolism has a strong genetic basis, with approximately 50-60% of the variance in incidence attributable to genetic effects. Some genetic susceptibility variants that contribute to risk have been identified in candidate genes, such as factor V Leiden and prothrombin.

The identification of the factor V Leiden (G1691A) missense mutation (Arg506Gln) causing factor V resistance to the anticoagulant action of activated protein C represents a landmark in understanding the basis of hereditary thrombotic risk. The FVL mutation is, in fact, the most common hereditary defect that predisposes to venous thrombosis

*§ J Res Med Sci. 2015 Jun; 20 (6):554-62. Factor V Leiden, factor V Cambridge, factor II GA20210, and methylenetetrahydrofolate reductase in cerebral venous and sinus thrombosis: A case-control study.*

*§ Laboratory biomarkers for venous thromboembolism risk in patients with hematologic malignancies: A review. Thromb Res. 2018 Mar; 163:138-145. doi: 10.1016/j.thromres.2018.01.037. Epub 2018 Jan 31.*

*§ Pregnancy, thrombophilia, and the risk of a first venous thrombosis: systematic review and bayesian meta-analysis. Croles FN, Nasserinejad K, Duvekot JJ, Kruip MJ, Meijer K, Leebeek FW. BMJ 2017; 359 doi: https://doi.org/10.1136/bmj.j4452*

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ISO 9001:2015
ISO 13485:2016

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| DESCRIPTION | LABEL | VOLUME | | STORAGE |
|---|---|---|---|---|
| | | GEN-001-25 | GEN-001-50 | |
| Mix oligonucleotides and probes | Mix G1691A FV Leiden 10X | 1 x 85 µl | 1 x 170 µl | -20°C |
| Mix buffer and Taq polymerase enzyme | Mix Real-Time PCR 2X | 1 x 425 µl | 1 x 850 µl | -20°C |
| Deionized $H_20$ | Deionized $H_20$ | 2 x 1 ml | 2 x 1 ml | -20°C |
| Genomic DNA or recombinant DNA | Control +1 | 1 x 22 µl | 1 x 22 µl | -20°C |
| Genomic DNA or recombinant DNA | Control +2 | 1 x 22 µl | 1 x 22 µl | -20°C |
| Genomic DNA or recombinant DNA | Control +3 | 1 x 22 µl | 1 x 22 µl | -20°C |

## TECHNICAL CHARACTERISTICS

COD. GEN-001-25 / COD. GEN-001-50

| | |
|---|---|
| STABILITY | 18 months |
| REAGENTS STATUS | Ready to use |
| BIOLOGICAL MATRIX | Genomic DNA extracted from whole blood, tissue, cells |
| POSITIVE CONTROL | Recombinant DNA for at least 3 analytical sessions |
| VALIDATED INSTRUMENTS | Biorad CFX96 Dx, Biorad Opus Dx e Agilent AriaDx, Hyris bCUBE, Hyris bCUBE3 with Hyris bAPP |
| TECHNOLOGY | Real-time PCR; oligonucleotides and specific probes; 2 FAM/HEX fluorescence channels |
| RUNNING TIME | 85 min |
| THERMAL CYCLING PROFILE | 1 cycle at 95 °C (10 min); 45 cycles at 95 °C (15 sec) + 60 °C (60 sec) |
| ANALYTICAL SPECIFICITY | Absence of non-specific pairings of oligonucleotides and probes; absence of cross-reactivity |
| ANALYTICAL SENSITIVITY : LIMIT OF DETECTION (LOD) | ≥ 0,016 ng of DNA |
| ANALYTICAL SENSITIVITY : LIMIT OF BLANK (LOB) | 0% NCN |
| REPRODUCIBILITY | 99,9% |
| DIAGNOSTIC SPECIFICITY / DIAGNOSTIC SENSITIVITY | 100%/98% |

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