REALQUALITY RS-FACTOR II G20210A

code RQ-27

Kit for detection and genotyping of mutation G20210A in the human gene coding for coagulation factor II by Real-Time PCR

CE IVD

INTRODUCTION

Phenomena of thrombophilia are commonly defined as blockage of blood circulation by clots, which originate in the veins or are stem from a thrombus in another area of the body. Thrombosis can be the result of events that activate the coagulation system, which include injury, surgery, immobilization, pregnancy and the use of estrogens and oral contraceptives. In addition, the genetic background of a person influences the individual risk of thrombosis.
Mutations in genes coding for factors of blood homeostasis and fibrinolysis may lead to a lifelong increased risk of thrombosis. Today, several of such genetic alterations are known.

Prothrombin, or **Factor II**, is the inactive precursor of thrombin. The gene comprises a 5'UTR, 14 exons, 13 introns and a 3'UTR. One known mutation in the 3'UTR is associated with elevated prothrombin levels and an increased risk of venous thrombosis. The role of this G→A transition at position 20210 is not yet fully understood, but several researchers have reported that heterozygous carriers of this mutation have by 30% higher prothrombin plasma levels than non-carriers and a three to six times higher risk to develop of deep-vein thrombosis compared to the general population. Although there are no data on homozygous carriers, researchers assume that the thrombosis risk of homozygous individuals is only slightly lower than that of persons homozygous for Factor V Leiden.
While this mutation is very rare among non-Caucasians, it can be found in 2% to 5% of Northern Europeans and 3% to 7% of Southern Europeans.
Using Real-Time PCR this mutation can be detected quickly and with high specificity and sensitivity.

TECHNICAL CHARACTERISTICS

Number of tests: 48 or 96

Shelf life: 12 months

Sample material: DNA extract from whole peripheral blood

Positive controls: contain target (DNA) sequences corresponding to following genotypes regarding mutation *Factor II G20120A*: homozygous wild-type (WT), homozygous mutated (MUT) and heterozygous (HET)

Compatible platforms: Validated on

- Applied Biosystems 7500 Fast / Fast Dx, 7300 and StepOnePlus / StepOne Real-Time PCR System
- Dx Real-Time System and CFX96 Real-Time PCR Detection System (Bio-Rad)

The kit can be used on instruments that allow a reaction volume of 25 µL and read the FAM and CAL Fluor® Orange 560 fluorescence (detection channels FAM and JOE/HEX).

Analytical specificity: No non-specific pairing of primers and probes

Analytical sensitivity: 2 ng / reaction of DNA

Diagnostic sensitivity and specificity: 100 %

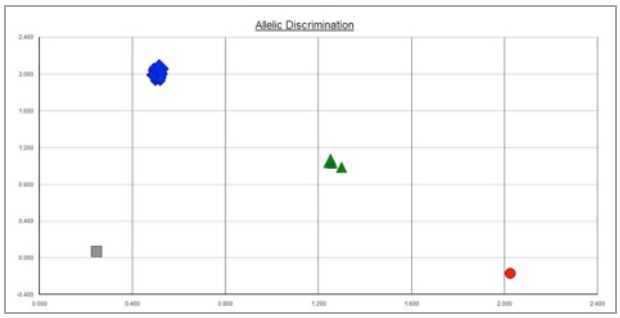

Fig. 1: Scatter plot on *Applied Biosystems 7500 Fast Dx Real-Time PCR System* using SDS software.

ORDERING INFORMATION

Code	Product	PKG
RQ-27-48/96	REALQUALITY RS-FACTOR II G20210A	48/96 tests

REFERENCES

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