AB-THROMBO TYPE PLUS

Code 04-71A

Kit for the simultaneous identification of mutations in the genes coding for Factor II, Factor V, MTHFR and PAI-1 by reverse line blot

CE IVD

INTRODUCTION

Vein thrombosis consists on the impediment of the blood circulation caused by blood clots formed or released locally inside the vein by a thrombus originated elsewhere. The sites in which blood clots form most commonly are the superficial and deep veins of the legs, but can also form in the veins of the brain, retina, liver and mesentery.

In addition to local factors that cause activation of the coagulation system such as trauma, surgery, immobilization, pregnancy and use of oral contraceptives, also the individual's genetic background may play an important role. The presence of mutations in genes encoding proteins involved in hemostatic and fibrinolytic processes may cause an increased risk of venous thrombosis during a lifetime.

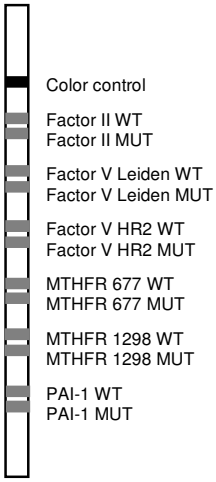
To date, numerous mutations have been identified responsible for the development of venous thrombosis: mutations in the gene encoding for Factor V, Factor II, methylene-tetrahydrofolate reductase (MTHFR) and inhibitor of the plasminogen activator type 1 (PAI-1).

It was also observed that the presence of multiple mutations may have synergistic effects: therefore, the possibility to simultaneously determine multiple mutations is of great value.

TEST PRINCIPLE

The **kit AB-THROMBO TYPE PLUS** is an IVD for the simultaneous identification of major mutations related to thrombosis by reverse line blot.

In particular, the following mutations were investigated by gene amplification and subsequent reverse allele specific hybridization: Factor II G20210A, Factor V Leiden G1691A (Arg505Gln), Factor V H1299R (HR2 haplotype), mutations of MTHFR C677T and A1298C polymorphism and the 4G/5G for PAI-1.



By overlaying the obtained strip with the trasparent film for strip reading you can quickly and easily determine the mutations that may be present and assess the status (homozygous, heterozygous, genetic compound)

TECHNICAL CHARACTERISTICS

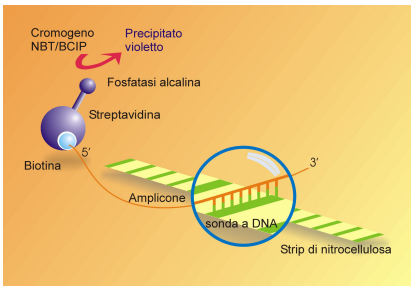
TEST NUMBER: 20 tests
STABILITY: 6 months
STARTING MATERIAL: extracted DNA
AMPLIFICATION: Ready-to-use single dose premixes
DETECTABLE MUTATIONS:

Factor II
G20210A (Prothrombin)
Factor V
G1691A (Factor V Leiden)
H1299R (haplotype HR2)
MTHFR
C677T
A1298C
PAI-1
4G/5G

ACCURACY: The accuracy of the test is 100%.
TIME FOR COMPLETION of Rev. Line Blot: about 1 hour 20 minutes.

PROCEDURE

1. **DNA AMPLIFICATION**: multiplex amplification premix, about 1.5 hour.
2. **AMPLIFICATE DENATURATION:** 5 minutes incubation at room temperature with the denaturing solution;
3. **HYBRIDIZATION:** 30 minutes at 46°C.
4. **COLORIMETRIC DETECTION:** 30 minutes with the conjugate at 46°C and 8 minutes of staining the strip by incubation with chromogenic (NBT / BCIP).



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