

# Devyser Thrombophilia

## Key advantages of the Devyser Thrombophilia

- One single mix allows testing of six relevant risk factors for thrombophilia
- Speed and ease of use: single tube PCR minimizes hands-on time
- Accurate and efficient: single tube PCR reduces analysis times while minimizing the risk of sample mix up

## Thrombophilia

Thrombophilia is an abnormality of blood coagulation, leading to increased risk for thrombosis. Thrombophilia can be identified in 50% of people who have an episode of thrombosis that was not provoked by other causes. Venous thrombosis is one of the most common thrombotic disorders affecting up to 2 in 1000 individuals every year and is associated with life-threatening conditions such as pulmonary embolism.

## Genetic risk factors for Thrombophilia

The predisposition to form blood clots can arise from mutations, acquired changes in the clotting mechanism or, more commonly, an interaction between genetic and acquired factors. The risk of thrombosis increases with the number of genetic and acquired risk factors present so that individuals with multiple risk factors are at greater risk than those with just a few.



## Devyser Thrombophilia

The Devyser Thrombophilia assay offers a very simple procedure for testing the most relevant mutations implicated in the risk of developing thrombophilia and venous thromboembolism (VTE).

It is a multiplex PCR reagent kit for simultaneous detection of six genetic risk factors associated with thrombophilia:

**Factor V Leiden, G1691A/R506Q:** one of the most important genetic risk factors for inherited thrombophilia, occurs in 20-50% of patients with VTE.

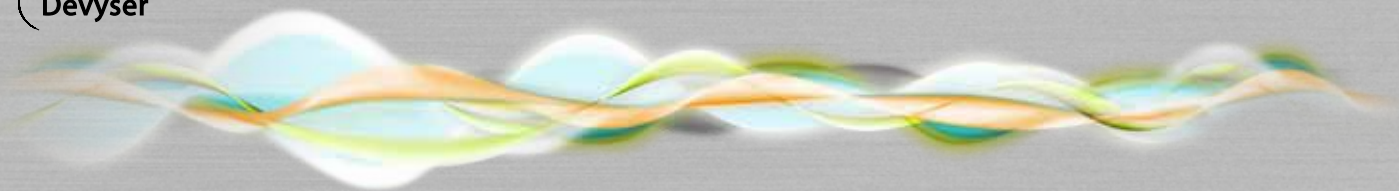
**Factor V R2 (H1299R):** Compound heterozygosity for FV R2 and FV Leiden is associated with an increased risk for venous thrombosis compared to that seen in FV Leiden heterozygotes alone.

**Prothrombin/Factor II (G20210A):** carriers have elevated risk for thrombosis; significantly increased risk in combination with FV Leiden.

**5,10-Methylenetetrahydrofolate Reductase (MTHFR),C677T:** homozygosity predisposes to thrombosis in the presence of additional risk factors.

**MTHFR, A1298C:** compound heterozygosity for MTHFR C677T and MTHFR A1298C is considered a risk factor for cardiovascular disease.

**Plasminogen Activator Inhibitor 1 (PAI-1/ SERPINE1) 4G/5G:** the 4G allele is considered to be a mild risk factor for VTE and Myocardial Infarction.



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## Technical Specification

Intended Use	The Devyser Thrombophilia kit is an in vitro diagnostic product for qualitative detection of genetic variants that may be associated with thrombophilia.
CE - labelled for IVD use	Yes
Detection format	ABI/Life Technologies Capillary electrophoresis instruments: 310, 3100, 3130, 3500, 3730
Parameters tested	Factor V Leiden, Factor V R2, Prothrombin/Factor II, MTHFR C677T, MTHFR A1298C, PAI-1/SERPINE1 4G/5G
Reaction volume	12,5 µL
Kit size	48 test
Article No.	8-A035
Accessories	<i>DNA Size marker:</i> 560 SIZER ORANGE (Art. No.: 8-A402)
Ready to use for PCR	Yes

## About Devyser

Devyser AB is specialized in the development, manufacturing and sales of diagnostic kits and reagents based on DNA analytical procedures, including PCR.

Devyser AB operates under strict quality control protocols and has an ISO13485:2012 (medical device) certification. Products are CE-labelled according to MDD 98/79/EC for use in in-vitro diagnostic procedures. The main areas of application for our products are prenatal diagnostics and clinical genetics.