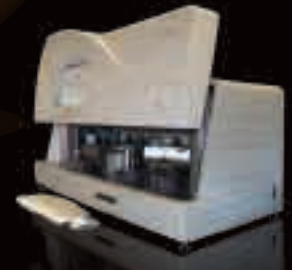


Factor II - V



Product Design

- ▶ The INFINITI™ System assay for Factor II & Factor V is 510(k) cleared for use as an aid to diagnosis in the evaluation of patients with suspected Thrombophilia.
- ▶ The INFINITI System Assay for Factor II & Factor V utilizes the FII-FV Intellipac™, FII-FV Amp Mix and FII-FV BioFilmChip™ Microarray.

Benefits

	VERSATILITY	◆	Multiplexed determination of 2 genetic variants on one BioFilmChip Microarray
	EFFICIENCY	◆	Rapid turnaround time enhances workflow efficiency
	AGILITY	◆	<i>Load N Go</i> automation with the INFINITI Analyzer
	INTEGRITY	◆	Replicate determinations on a single BioFilmChip Microarray ensure quality results

Genetic Variants

Factor II (Prothrombin): G20210A
Factor V Leiden: G1691A

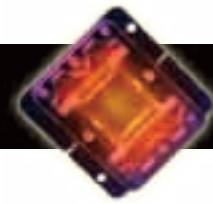
Sample Type and Volume

0.2 - 2.0 ml of peripheral whole blood in EDTA (purple-top) tube
50 ng DNA / reaction

Product Information

Product No.	Product Name	Description	Pack Size
01 105	INFINITI FII-FV BioFilmChip	12 BioFilmChips/magazine	4 Magazines / pack
01 205	INFINITI FII-FV Intellipac	24 tests/IntelliPac	2 Intellipac / pack
01 305	INFINITI FII-FV Amp Mix	250 ul/vial	4 vials / pack

The INFINITI Factor II - Factor V Panel assay is available to molecular testing laboratories as an **in-vitro diagnostic assay, (IVD)**. Please contact AutoGenomics to obtain product information.



Clinical Relevance

- ▶ The Factor V Leiden mutation is the most common variant associated with inherited thrombosis.¹
- ▶ The Factor V Leiden mutation is supported by a high prevalence in the general population (4-6% of US population), and accounts for 85-95% of activated protein C resistant cases.¹
- ▶ Presence of the Factor V Leiden variant enhances the risk of venous thrombosis, with odds ratios (ORs) of 3 to 8 in heterozygotes and 30 to 140 in homozygotes.²
- ▶ The Factor II (prothrombin) variant gene is the second most common genetic defect for inherited thrombosis.

Clinical Utility

- ▶ "The increased risk of venous thrombosis in patients who are heterozygous for the prothrombin (G20210A) gene polymorphism is 3-fold."³
- ▶ "Homozygotes for this polymorphism have been described but are very uncommon."³
- ▶ Patients with a previous, or current, thrombotic event that have the prothrombin (G20210A) gene polymorphism are potentially at increased risk for recurrence.
- ▶ "Patients with the prothrombin (G20210A) mutation are at increased risk of thrombosis when exposed to other risk factors such as:
 - (1) smoking
 - (2) pregnancy
 - (3) Obesity
 - (4) Oral Contraceptives
 - (5) Immobility¹
- ▶ "The risk of thrombosis is substantially increased for patients with multiple genetic risk factors (i.e., the "double hit hypothesis") including the prothrombin (G20210A) gene mutation, Factor V Leiden mutation, hyperhomocysteinemia, methylenetetrahydrofolate reductase (MTHFR) thermolabile polymorphism, protein C deficiency, protein S deficiency, and antiphospholipid antibody syndrome(s)."¹
- ▶ Definition and confirmation of the prothrombin (G20210A) gene polymorphism is necessary for genetic counseling of patients for themselves and family members.¹

References

1. Grody W, Griffin J, Taylor A, Korf B, Heit, J. (2001) American College of Medical Genetics Consensus Statement on Factor V Leiden Mutation Testing, *Genetics in Medicine*, 3:2, 139-147.
2. Salomon, O., et.al., Single and Combined Prothrombotic Factors in Patients With Idiopathic Venous Thromboembolism, *Arterioscler Thromb Vasc Biol*. 1999;19:511-518.
3. <http://pathology.mc.duke.edu/coag/PTGlflyer2.html>