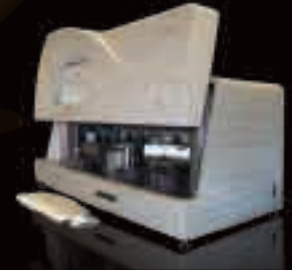


# Factor V

# SPOT ON INFINITI™

*The Automated Multiplexing MDx Solution*



## Product Design

- ▶ The INFINITI™ System Assay for 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 V is used to determine genetic variants in Factor V Leiden.
- ▶ The INFINITI System Assay for Factor V utilizes the Factor V Intellipac™, Factor V Amp Mix and Factor V BioFlimChip™ Microarray.

## Benefits

	VERSATILITY	◆	Determination of genetic variant for Factor V Leiden
	EFFICIENCY	◆	Rapid turnaround time enhances workflow efficiency
	AGILITY	◆	<i>Load N Go</i> automation with the INFINITI Analyzer
	INTEGRITY	◆	Replicate determinations on a single BioFlimChip Microarray ensure quality results

## Genetic Variants

Factor V Leiden	G1691A
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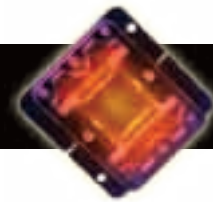
## Sample Type and Volume

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

Product No.	Product Name	Description	Pack Size
01 103	INFINITI FV BioFilmChip	12 BioFilmChips/magazine	4 Magazines / pack
01 203	INFINITI FV Intellipac	24 tests/IntelliPac	2 Intellipac / pack
01 303	INFINITI FV Amp Mix	250 ul/vial	4 vials / pack

The INFINITI Factor V 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.
- ▶ This mutation has a high prevalence in the general population (4 - 6% of US Population), and accounts for 85-95% of activated protein C resistant cases.<sup>1</sup>
- ▶ Enhanced risk of venous thrombosis, with the presence the Factor V Leiden variant, with odds ratios (ORs) of 3 to 8 in heterozygotes and 30 to 140 OR in homozygotes.<sup>2</sup>

## Clinical Utility<sup>3</sup>

- ▶ The risk of thrombosis is substantially increased for patients with multiple genetic risk factors (i.e. The "double hit hypothesis") including factor V Leiden mutation, hyperhomocysteinemia, protein C deficiency, protein S deficiency and antiphospholipid antibody syndrome(s).

## 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;
3. *Arteriosclerosis Thrombosis and Vascular Biology*, 1999, 19:511-518 © 1999 American Heart Association  
<http://pathology.mc.duke.edu/coag/PTGI flyer2.html>