

Factor II

SPOT ON INFINITI™

The Automated Multiplexing MDx Solution



Product Design

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

Benefits

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

Genetic Variants

Factor II (Prothrombin) G20210A

Sample Type and Volume

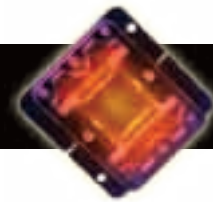
0.2 - 2.0 ml of peripheral whole blood in EDTA (purple-top) tube
50 ng DNA / reaction

Product Information

Product No.	Product Name	Description	Pack Size
01 102	INFINITI FII BioFilmChip	12 BioFilmChips/magazine	4 Magazines / pack
01 202	INFINITI FII Intellipac	24 tests/IntelliPac	2 Intellipac / pack
01 302	INFINITI FII Amp Mix	250 ul/vial	4 vials / pack

The INFINITI Factor II 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 II variant (Prothrombin 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.¹
- ▶ Homozygotes for this polymorphism have been described but are very uncommon.¹
- ▶ Patients with a previous, or current, thrombotic event that have the prothrombin (G20210A) gene polymorphism are potentially at increased risk for recurrence.¹
- ▶ 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. <http://pathology.mc.duke.edu/coag/PTGIflyer2.html>