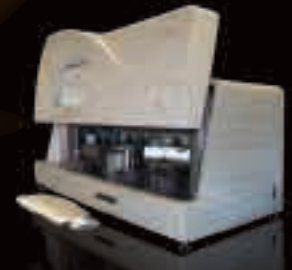


FII-FV-MTHFR Panel

SPOT ON

INFINITI™

The Automated Multiplexing MDx Solution



Product Design

- ▶ The INFINITI™ FII-FV-MTHFR Panel Assay is designed to identify patients with genetic variants of Factor II, Factor V, and MTHFR genes.
- ▶ The INFINITI FII-FV-MTHFR Panel Assay utilizes the FII-FV-MTHFR Intellipac™, FII-FV-MTHFR Amp Mix and FII-FV-MTHFR BioFilmChip™ Microarray.
- ▶ The INFINITI FII-FV-MTHFR Panel Assay is automated by the 510(k) cleared INFINITI Analyzer.
- ▶ Clinical Studies to support a 510(k) application are currently in progress.

Benefits

	VERSATILITY	◆	Simultaneous Multiplexed determination of 4 genetic variants for Factor II (Prothrombin), Factor V Leiden, and MTHFR
	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
MTHFR	A1298C and C677T

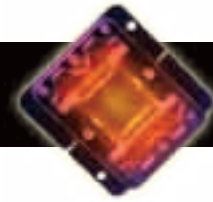
Sample Type and Volume

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
01 101	INFINITI FII-V- MTHFR BioFilmChip	12 BioFilmChips/magazine	4 Magazines / pack
01 201	INFINITI FII-V- MTHFR Intellipac	24 tests/IntelliPac	2 Intellipac / pack
01 301	INFINITI FII-V- MTHFR Amp Mix	250 ul/vial	4 vials / pack

Please contact AutoGenomics to obtain product information and for product status updates.



Clinical Relevance

- ▶ The Factor V Leiden mutation is the most common variant associated with inherited thrombosis.
- ▶ This 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
- ▶ Enhanced risk of venous thrombosis is associated with the presence the Factor V Leiden variant, with odds ratios (ORs) of 3 to 8 in heterozygotes and 30 to 140 in homozygotes.²
- ▶ Methylenetetrahydrofolate reductase (MTHFR) is a key enzyme in the metabolism of homocysteine.⁴
- ▶ Elevated homocysteine levels have been associated with fetal neural tube defects (NTDs), miscarriages, and also indicate an increased risk factor for blood clots, arteriosclerosis, and strokes in both men and women.⁴

Clinical Utility

- ▶ "The increased risk of venous thrombosis in patients who are heterozygous for the prothrombin (G20210A) gene polymorphism is 3-fold."³
- ▶ "Patients with a previous, or current, thrombotic event that have the prothrombin (G20210A) gene polymorphism are potentially at increased risk for recurrence."³
- ▶ Homozygosity for a nucleotide variant in the methylenetetrahydrofolate reductase (MTHFR) gene leads to increased plasma homocysteine levels, another risk factor for venous thrombosis.
- ▶ "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)."³

References

1. Grody W, et.al., American College of Medical Genetics Consensus Statement on Factor V Leiden Mutation Testing, *Genetics in Medicine*, 2001, 3(2), p.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/PTGIflyer2.html>
4. Ilan Weisberg, et.al., A Second Genetic Polymorphism in Methylenetetrahydrofolate Reductase (MTHFR) Associated with Decreased Enzyme Activity, *Molecular Genetics and Metabolism*, Volume 64, Issue 3, July 1998, Pages 169-172.