

Warfarin Assay

SPOT ON INFINITI™


The Automated Multiplexing MDx Solution



Product Design

- ▶ The INFINITI™ Warfarin Assay is 510(k) cleared for use to identify individuals at risk for sensitivity to Warfarin.
- ▶ The INFINITI Warfarin Assay utilizes the Warfarin Assay Intellipac™, Warfarin Assay Amplification Mix and the Warfarin Assay BioFilmChip™ Microarray.
- ▶ The INFINITI Warfarin Assay is automated by the 510(k) cleared INFINITI Analyzer.

Benefits

	VERSATILITY	◆	Multiplexed determination of 3 genetic variants on one BioFilmChip Microarray
	EFFICIENCY	◆	Rapid turnaround time allows for same day dosing
	AGILITY	◆	<i>Load N Go</i> automation with the INFINITI Analyzer
	INTEGRITY	◆	Replicate determinations on a single BioFilmChip Microarray ensure quality results

Genetic Variants

2C9 Variants: *2, *3
Clinical Relevance *2, *3 are the commonly identified variants shown to decrease enzymatic activity.

VKORC1 Variants: 3673 (-1639G>A)
Clinical Relevance 3673 = (-1639G>A) is the commonly identified VKORC1 variant and could be predictive of an individual's response to Warfarin.

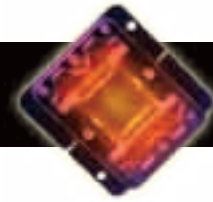
Sample Type and Volume

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
03 114	INFINITI Warfarin Assay BioFilmChip	12 BioFilmChips/magazine	4 Magazines / pack
03 214	INFINITI Warfarin Assay Intellipac	24 tests/IntelliPac	2 Intellipac / pack
03 314	INFINITI Warfarin Assay Amp Mix	250 ul/vial	4 vials / pack

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



Clinical Relevance

- ▶ Warfarin is the most widely prescribed oral anticoagulant that acts by inhibiting vitamin K-dependent coagulation factors.
- ▶ Warfarin is used to treat various disorders, including venous thrombosis, atrial fibrillation, pulmonary embolism, acute myocardial infarction and following heart valve replacement.
- ▶ In the US, more than 3,000,000 new prescriptions are being written every year, and the total number of warfarin prescriptions has increased by 45 percent between 1999 and 2004.
- ▶ There is greater than a ten-fold inter-patient variability in the dose required to attain a therapeutic response.

Warfarin Adverse Effects

- ▶ Warfarin exposes patients to increased risk of hemorrhage.
- ▶ Annual incidence of associated major bleeding complications has ranged from 1.0% to 5.0%.
- ▶ Annual incidence of fatal hemorrhages has been reported as 0.5% to 1.1%.¹
- ▶ Major bleeding occurred during the first 90 days of treatment in 50% of patients.¹
- ▶ Adverse effects of warfarin treatment account for 15 percent of all severe adverse effects.
- ▶ Optimal use of the drug has been hampered by its greater than 10-fold inter-patient variability in the doses required to attain therapeutic response.²

Clinical Utility

Influence of CYP2C9-VKORC1 on dosing²

Reference	2C9	VKORC1	Weight, Age, 2C9, VKORC1, Other Factors
D'Andrea et al	22%	14%	---
Rieder et al	6%	21%	---
Bodin et al	14%	37%	54%
Sconce et al	18%	15%	54%
Wadelius et al	12%	30%	56%
Veenstra et al	8%	31%	61%
Kimura et al	5%	11%	33%



References

1. Fanikos, John, et. al. Major bleeding complications in a specialized anticoagulation service. American Journal of Cardiology. 2005; 96: 595-98.
2. Yin, T, & Miyata, T. Warfarin dose and the pharmacogenomics of CYP2C9 and VKORC1-rationale and perspectives. Thrombosis Research. 2007; 120: 1-10.