

UGT1A1

SPOT ON INFINITI™


The Automated Multiplexing MDx Solution



Product Design

- ▶ The INFINITI™ UGT1A1 Assay is designed to identify patients with UGT1A1 genetic variants.
- ▶ The INFINITI UGT1A1 Assay utilizes the UGT1A1 Intellipac™, UGT1A1 Amp Mix and UGT1A1 BioFilmChip™ Microarray.
- ▶ The INFINITI UGT1A1 Assay is automated by the 510(k) cleared INFINITI Analyzer.
- ▶ Clinical studies to support a 510(k) application are currently in progress.

Benefits

	VERSATILITY	◆	Multiplexed determination of 4 genetic variants on one BioFilmChip Microarray
	EFFICIENCY	◆	Detection of duplications in the TATA box promoter region provides accurate analysis
	AGILITY	◆	<i>Load N Go</i> automation with the INFINITI™ Analyzer
	INTEGRITY	◆	Replicate determinations on a single BioFilmChip Microarray ensure quality results

Genetic Variants

UGT1A1: *1, *28, *36, *37

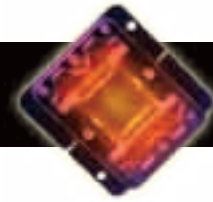
Sample Type and Volume

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
03 105	INFINITI UGT1A1 BioFilmChip	12 BioFilmChips/magazine	4 Magazines / pack
03 205	INFINITI UGT1A1 Intellipac	24 tests/IntelliPac	2 Intellipac / pack
03 305	INFINITI UGT1A1 Amp Mix	250 uL/vial	4 vials / pack

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



Clinical Relevance

- ▶ SN-38, an active metabolite of irinotecan, is detoxified to an inactive glucuronidated form by uridine diphosphate glucuronosyltransferase isoform 1A1 (UGT1A1) and excreted.¹
- ▶ Identification of the UGT1A1 *1, *28, *36 and *37 alleles has been shown to assist physicians when determining specific dosages of irinotecan for individual patients, thus reducing toxicity associated with the drug.²
- ▶ Individuals who are homozygous for the UGT1A1*28 allele are at increased risk for neutropenia following initiation of CAMPTOSAR treatment. A reduced initial dose should be considered for patients known to be homozygous for the UGT1A1*28 allele.³

Clinical Utility

Summary of Allele Prevalence and Risk of Toxicity in Caucasian Population⁴

Group	Prevalence	Risk of Toxicity
All Patients	---	10%
Patients that are *28/*28	10%	50%
Patients that are *1/*28	40%	12.5%
Patients that are *1/*1	50%	0

- ▶ UGT 1A1*37 polymorphism also results in high levels of active metabolite SN 38, thus *37 also presents a risk for neutropenia.
- ▶ UGT 1A1*36 polymorphism enhances the metabolism of SN 38, thus *36 tolerate a higher irinotecan dosage.

References

1. Jeffrey A. Meyerhardt, MD, MPH, R.J. Mayer, MD, "Systemic Therapy for Colorectal Cancer," NEJM Vol. 352, 2005, p.476-487.
2. "How Long Will It Take For Oncologists To Embrace UGT1A1 Testing?" Diagnostic Testing and Technology Report. Feb. 2006. VI(6):5-7
3. Pfizer website. www.pfizer.com
4. Innocenti F, Undevia SD, Iyer L, et al. Genetic variants in the UDP-glucuronosyl-transferase1A1 gene predict the risk of severe neutropenia of Irinotecan, Journal of Clinical Oncology, Vol 22, No 8 (April 15), 2004; pp.1382-1388.