SLCO1B1 GENE POLYMORPHISM (SLCO1B1 c.521 T>C, SLCO1B1 c.388 A>G, SLCO1B1 g.-11187 G>A)

For in vitro diagnostic use

CE IVD

ORDERING INFORMATIONS

REF: FGC-007-25
RDM Code: 12248810/R
CND Code: W010699
Tests: 25
Reactions: 31 x 3
Manufacturer: BioMol Laboratories s.r.l.

CONTENTS OF THE KIT

The kit consists of: reagents for Real-Time PCR amplification
**the reagents for the extraction of genomic DNA are not supplied in the kit.*

PRODUCT CHARACTERISTICS

Device belonging to the family of in vitro medical devices **REAL-TIME QUALITATIVE PCR-PHARMACOGENETICS TEST**. Detection of genetic variants SLCO1B1 c.521 T>C (rs4149056, V174A), SLCO1B1 c.388 A>G (rs2306283, N130D), SLCO1B1 g.-11187 G>A (rs4149015) of the gene SLCO1B1 by amplification with oligonucleotides and specific probes (allele-specific genotyping) and subsequent detection with qPCR-Real-time. Kit optimized for Real-Time PCR instrumentation Biorad CFX96 Dx, Biorad Opus Dx and Agilent AriaDx.

SCIENTIFIC BACKGROUND

Most drug transporters are involved in drug biotransformation by playing an important role in the pharmacokinetic process including drug absorption, distribution and elimination. Genetic polymorphisms of these transporters can influence the pharmacokinetic process. Among the groups belonging to the transmembrane protein transporters we find the superfamily of solute-linked transporters SLC (solute-linked carrier) or better known as influx transporters, which absorb the substrate through the cells.
Among the various influx transporters involved in the uptake of drugs and organic compounds from the blood into the cell is OATPs, the organic anion transporter of polypeptides expressed in many organs such as the intestine, liver and kidney. Functional changes in OATPs transporters can affect response and tolerance to many drugs. Genetic variations in the SLCO1B1 gene, located on chromosome 12p12.1 and coding for OATP1B, a sodium-independent bile acid transporter that generally transports amphipathic molecules across the basolateral membrane of hepatocytes, have been reported in several populations.

CLINICAL SIGNIFICANCE

Polymorphisms of the SLCO1B1 gene reduce the functionality of OATP1B1 causing adverse drug reactions (ADRs). Genetic variants include SLCO1B1 c.388 A>G (rs2306283, N130D), SLCO1B1 c.521 T>C (rs4149056, V174A), and SLCO1B1 g.-11187 G>A (rs4149015). The most frequent and widely investigated haplotypes in various ethnic groups are SLCO1B1 c.388 A>G and SLCO1B1 c.521 T>C.
The c.521 T>C genotype is associated with a reduced cholesterol-lowering efficacy compared to the c.521TT genotype, while the c.388 A>G genotype leads to a large reduction in transport activity compared to the wild type genotype inducing myopathies in patients who take statins.

§ Mizuno N, Sugiyama Y. Drug transporters: their role and importance in the selection and development of new drugs. Drug Metab Pharmacokinet. 2002; 17 (2):93–108. doi:10.2133/dmpk.17.932.

§ Franke RM, Gardner ER, Sparreboom A. Pharmacogenetics of Drug Transporters. Curr Pharm Des. 2010; 16 (2):220–230. doi: 10.2174/ 138161210790112683 5.

§ Gong, I. Y., and Kim, R. B. (2013). Impact of genetic variation in OATP transporters to drug disposition and response. Drug Metab. Pharmacokinet. 28(1), 4–18. doi: 10.2133/dmpk.DMPK-12-RV-099.

§ Na Nakorn C, Waisayarat J, Dejthevaporn C, Srisawasdi P, Wongwaisayawan S, Sukasem C. Genetic Variations and Frequencies of the Two Functional Single Nucleotide Polymorphisms of SLCO1B1 in the Thai Population.. Front Pharmacol. 2020 Jun 5; 11: 728. doi: 10.3389/fphar.2020.00728. eCollection 2020. PMID: 32581780.

§ SLCO1B1 and ABCG2 Gene Polymorphisms in a Thai Population. Pharmgenomics Pers Med. 2020 Oct 22; 13: 521-530. doi: 10.2147/PGPM.S268457. eCollection 2020.

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ISO 9001:2015
ISO 13485:2016

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DESCRIPTION	LABEL	VOLUME	STORAGE
		FGC-007-25	
Mix oligonucleotides and probes	Mix 10X SLCO1B1 c.521 T>C	1 x 85 µl	-20°C
Mix oligonucleotides and probes	Mix 10X SLCO1B1 c.388 A>G	1 x 85 µl	-20°C
Mix oligonucleotides and probes	Mix 10X SLCO1B1 g.-11187 G>A	1 x 85 µl	-20°C
Mix buffer and Taq-polymerase enzyme	Mix Real-Time PCR 2X	1 x 1275 µl	-20°C
Deionized H_2O	Deionized H_2O	2 x 1 ml	-20°C
Genomic DNA or recombinant DNA	Control +1 Homozygous **TT SLCO1B1 c.521** Homozygous **AA SLCO1B1 c.388** Homozygous **GG SLCO1B1 g.-11187**	1 x 40 µl	-20°C
Genomic DNA or recombinant DNA	Control +2 Heterozygous **TC SLCO1B1 c.521**	1 x 20 µl	-20°C
Genomic DNA or recombinant DNA	Control +3 Heterozygous **AG SLCO1B1 c.388**	1 x 20 µl	-20°C
Genomic DNA or recombinant DNA	Control +4 Heterozygous **GA SLCO1B1 g.-11187**	1 x 20 µl	-20°C

TECHNICAL CHARACTERISTICS

COD. FGC-007-25

STABILITY	18 months
REAGENTS STATUS	Ready to use
BIOLOGICAL MATRIX	Genomic DNA extracted from whole blood, tissue, cells
POSITIVE CONTROL	Recombinant DNA for at least 3 analytical sessions
TECHNOLOGY	Real-time PCR; oligonucleotides and specific probes; 2 FAM/HEX fluorescence channels
VALIDATED INSTRUMENTS	Biorad CFX96 Dx, Biorad Opus Dx e Agilent AriaDx
RUNNING TIME	85 min
THERMAL CYCLING PROFILE	1 cycle at 95 °C (10 min); 45 cycles at 95 °C (15 sec) + 60 °C (60 sec)
ANALYTICAL SPECIFICITY	Absence of non-specific pairings of oligonucleotides and probes; absence of cross-reactivity
ANALYTICAL SENSITIVITY : LIMIT OF DETECTION (LOD)	≥ 0,016 ng of DNA
ANALYTICAL SENSITIVITY : LIMIT OF BLANK (LOB)	0% NCN
REPRODUCIBILITY	99,9%
DIAGNOSTIC SPECIFICITY / DIAGNOSTIC SENSITIVITY	100%/98%

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