

CYP3A4 *22 GENETIC VARIANT

ORDERING INFORMATION

REF: FGC-017-25
Tests: 25
Reactions: 31
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 devices **REAL-TIME QUALITATIVE PCR-GENETIC VARIANTS- RESEARCH USE ONLY.** Detection of genetic variant *22 (rs 35599367) of the CYP3A4 gene by amplification with oligonucleotides and specific probes (allele-specific genotyping) and subsequent detection with qPCR-Real-time. Kit optimized for Real-time PCR instruments Biorad CFX96 Dx, Biorad Opus Dx, Agilent AriaDx, Thermofisher QuantStudio™ 5 Real-Time PCR System.

SCIENTIFIC BACKGROUND

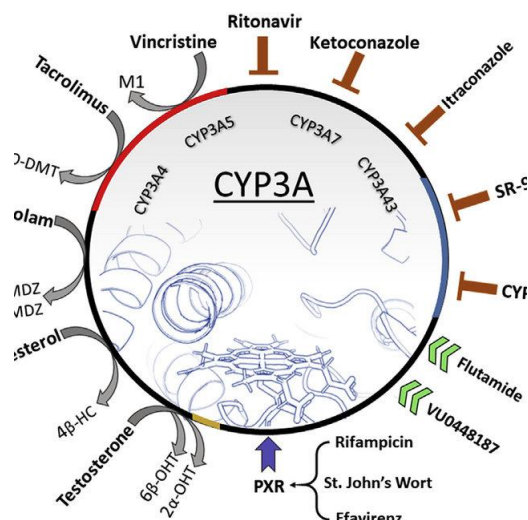
Cytochrome P450 3A4 (CYP3A4) is the most important drug metabolizing enzyme in the liver, responsible for the oxidative metabolism of 50% of clinically prescribed drugs.

It metabolises numerous compounds that are clinically, physiologically and toxicologically important. The expression of CYP3A4 varies 40-fold in individual human livers, and the metabolism of CYP3A4 substrates varies at least 10-fold in vivo. Therefore, genetic variation in CYP3A4 could potentially affect the pharmacokinetics, toxicity and clinical outcome of drug treatment.

§ Clin Transl Sci. 2025 Apr;18(4):e70173. CYP3A Genotype Is Associated With Variability in the Exposure and Clearance of the Novel Oncogenic Transcription Inhibitor Lurbinectedin
§ Meta-Analysis Eur J Clin Pharmacol. 2025 Mar;81(3):403-417. Pharmacogenetics of opioid medications for relief of labor pain and post-caesarean pain: a systematic review and meta-analysis
§ Review Front Genet. 2021 Jul 8;12:711943. CYP3A4*22 Genotyping in Clinical Practice: Ready for Implementation?
§ Front Genet. 2020 Aug 21;11:944. Inherited and Acquired Determinants of Hepatic CYP3A Activity in Humans.

CLINICAL SIGNIFICANCE

A total of 28 SNPs have been identified. A new CYP3A4 allele (defined by 15389 C>T, rs35599367, CYP3A4*22) with a frequency of 5-7% in the Caucasian population, which is associated with low hepatic CYP3A4 expression and CYP3A4 activity and has effects on the metabolism of statins, tacrolimus and cyclosporine.



CYP3A4 *22 GENETIC VARIANT

ORDERING INFORMATION

REF: FGC-017-25
Tests: 25
Reactions: 31
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.



CONTENTS OF THE KIT

DESCRIPTION	LABEL	VOLUME	STORAGE
		FGC-017-25	
Mix oligonucleotides and probes	Mix 10X CYP3A4 *22	1 x 62 µl	-20°C
Mix buffer and Taq-polymerase enzyme	Mix Real-Time PCR 2X	1 x 310 µl	-20°C
Deionized H ₂ O	Deionized H ₂ O	1 x 1 ml	-20°C
Genomic DNA or recombinant DNA	Control 1	1 x 22 µl	-20°C
Genomic DNA or recombinant DNA	Control 2	1 x 22 µl	-20°C

TECHNICAL CHARACTERISTICS

COD. FGC-017-25

STABILITY	18 months
REAGENTS STATUS	Ready to use
BIOLOGICAL MATRIX	Genomic DNA extracted from whole blood, tissues, cells
POSITIVE CONTROLS	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 and Agilent AriaDx, Thermofisher QuantStudio™ 5 Real-Time PCR System.
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
LIMIT OF DETECTION (LOD)	≥ 5 ng of genomic DNA
LIMIT OF BLANK (LOB)	>40 Cq
REPRODUCIBILITY	99,9%
SPECIFICITY / SENSITIVITY	99,9%/98%