# GSTP1 GENE VARIANT A313G (I105V)

For in vitro diagnostic use

CE IVD

## ORDERING INFORMATIONS

*REF: FGC-004-25*
*RDM Code: 1875567/R*
*CND Code: W0106010499*
*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 medical devices **REAL-TIME QUALITATIVE PCR-PHARMACOGENETICS TEST**. The FGC-004 kit allows the characterization of the A313G genetic variant of the GSTP1 gene (rs1695) 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

The GSTP1 gene is located on chromosome 11q13 and has numerous polymorphisms. A single nucleotide substitution (rs1695) A/G causes an amino acid substitution from isoleucine to valine (I105V). This results in reduced substrate specificity, catalytic activity and thermal stability in the GSTP1 protein which is an isoenzyme with an important role in the detoxification of carcinogens, the metabolism of chemotherapeutic agents and the regulation of the cell cycle and apoptosis.

## CLINICAL SIGNIFICANCE

Numerous studies in the literature have investigated the correlation between the GSTP1 rs1695 variant and various treatment outcomes, including survival and clinical response, in patients suffering from malignant tumors.
Recently, a significant correlation has been demonstrated between GSTP1 polymorphism and toxicity from platinum derivatives with symptoms such as vomiting and development of skin ulcers in patients affected by colorectal cancer (AA genotype for GSTP1 shows lower rates of severe vomiting (35.3 %) compared to patients with AG and GG genotypes (66.7% and 100%, respectively, p = 0.027).
A 2022 meta-analysis study showed that patients receiving platinum-based treatment with the rs1695 G allele had approximately 1.7 and 2.6 times higher haematological adverse events and neutropenia than those with the AA genotype, respectively. Hematological toxicity and neutropenia are serious adverse events leading to treatment discontinuation. In this context, the results of this study indicated that GSTP1 could serve as a potential marker and substantially influence treatment regimens (level 3, PHARMG KB).


§ Association between Genetic Polymorphism of GSTP1 and Toxicities in Patients Receiving Platinum-Based Chemotherapy: A Systematic Review and Meta-Analysis. Pharmaceuticals (Basel) 2022 Apr 1;15(4):439.
§ Evaluating the role of GSTP1 genetic polymorphism (rs1695, 313A>G) as a predictor in cyclophosphamide-induced toxicities. Medicine 100(11): p e24423, March 19, 2021.
§ Glutathione S-transferasesP1 AA (105Ile) allele increases oral cancer risk, interacts strongly with c-Jun Kinase and weakly detoxifies areca-nut metabolites. Sci Rep 2020 Apr 7;10(1):6032 doi:10.1038/s41598-020-63034-3.
§ Predictive value of clinical toxicities of chemotherapy with fluoropyrimidines and oxaliplatin in colorectal cancer by DPYD and GSTP1 gene polymorphisms. World Journal of Surgical Oncology volume 18, Article number: 321 (2020).
§ GSTP1 and cancer: Expression, methylation, polymorphisms and signaling (Review). Int J Oncol 2020 Apr;56(4):867-878. doi: 10.3892/ijo.2020.4979.
§ Glutathione S-Transferase Pi 1 (GSTP1) Gene 313 A/G (rs1695) polymorphism is associated with the risk of urinary bladder cancer: Evidence from a systematic review and meta-analysis based on 34 case-control studies. Gene. 2019 Nov 30; 719: 144077. doi: 10.1016/j.gene.2019.144077. Epub 2019 Aug 24.
§ Relationship between GSTP1 rs1695 gene polymorphism and myelosuppression induced by platinum-based drugs: a meta-analysis. Int J Biol Markers. 2018 Sep 21:1724600818792897. doi: 10.1177/1724600818792897.
§ Genotypes Affecting the Pharmacokinetics of Anticancer Drugs. Clin Pharmacokinet. 2017, Apr; 56 (4):317-337. doi: 10.1007/ s40262-016-0450-z. Review.
§ Association of glutathione S-transferase T1, M1, and P1 polymorphisms in the breast cancer risk: a meta-analysis. Ther Clin Risk Manag. 2016 May 12; 12: 763-9. doi: 10.2147/TCRM.S104339. eCollection 2016.
§ Predictive potential role of glutathione S-transferase polymorphisms in the prognosis of breast cancer. Genet Mol Res. 2015 Aug 28; 14 (3):10236-41. doi: 10.4238/2015.August.28.7.



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EN ISO 9001 CERTIFICATE
EN ISO 13485 CERTIFICATE



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| DESCRIPTION | LABEL | VOLUME | STORAGE |
|---|---|---|---|
| | | FGC-004-25 | |
| Mix oligonucleotides and probes | Mix 10X A313G GSTP1 | 1 x 85 µl | -20°C |
| Mix buffer and Taq-polymerase enzyme | Mix Real-Time PCR 2X | 1 x 425 µl | -20°C |
| Deionized $H_20$ | Deionized $H_20$ | 2 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 |
| Genomic DNA or recombinant DNA | Control +3 | 1 x 22 µl | -20°C |

## TECHNICAL CHARACTERISTICS

| COD. FGC-004-25 | |
|---|---|
| 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 genomic DNA |
| ANALYTICAL SENSITIVITY: LIMIT OF BLANK (LOB) | 0% NCN |
| REPRODUCIBILITY | 99,9% |
| DIAGNOSTIC SPECIFICITY / DIAGNOSTIC SENSITIVITY | 100%/98% |

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