GENETIC VARIANT ARG399GLN OF THE XRCC1 GENE

For in vitro diagnostic use

CE IVD

ORDERING INFORMATIONS

REF: FGC-011-25
RDM Code: 2259495/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**
Determination of the G399A G>A polymorphism of the XRCC1 gene (ARG399GLN) 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, Biorad Opus Dx, Agilent AriaDx.

SCIENTIFIC BACKGROUND

Radiotherapy is a potentially curative and important therapeutic option in the early stages of localized carcinoma. Radiotherapy and cytotoxic treatment destroy cancer cells by inducing DNA damage. Therefore, the outcome of these treatments depends on the effectiveness of DNA repair systems. The XRCC1 (X-Ray repair cross complementing group 1) protein is essentially involved in both single-strand break repair and base excision repair. The single nucleotide polymorphism (SNPs) of the XRCC1(rs25487) gene identifies the G399A G>A mutation and involves the substitution in codon 399 of the amino acid arginine (Arg) to the amino acid glutamine (Gln).

CLINICAL SIGNIFICANCE

Studies have been conducted on the functional effects of the amino acid substitution Arg399Gln. Such studies suggested that the AA variant genotype is associated with a 3- to 4-fold reduced DNA repair capacity.
Furthermore, it has also been associated with an increase in chromosomal deletions.
Genotypes containing, however, wild-type alleles (GG and AG)
show a reduced risk of recurrence or death among patients with metastatic breast cancer receiving chemotherapy.

§ XRCC1 rs25487 Polymorphism Predicts the Survival of Patients After Postoperative Radiotherapy and Adjuvant Chemotherapy for Breast Cancer ANTICANCER RESEARCH 34: 3031-3038 (2014)
§ Genetic polymorphisms in XRCC1 associated with radiation therapy in prostate cancer Cancer Biology & Therapy 10:1, 13-18; July 1, 2010;
§ Functional characterization of polymorphisms in DNA repair genes using cytogenetic challenge assays. Environ Health Perspect 111: 1843-1850, 2003.
ANTICANCER RESEARCH 34: 3031-3038 (2014) 3036

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ISO 9001:2015
ISO 13485:2016

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DESCRIPTION	LABEL	VOLUME	STORAGE
		FGC-011-25	
Mix oligonucleotides and probes	Mix 10X Arg399Gln XRCC1	1 x 85 µl	-20°C
Mix buffer and Taq-polymerase enzyme	Mix Real-Time PCR 5X	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-011-25	
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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