BRAF V600E (T1799A) MUTATION

For in vitro diagnostic use

CE IVD

ORDERING INFORMATIONS

REF: ONC-021-25
CND Code: W01060299
RDM Code: 1703276/R
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

Qualitative detection of V600E mutation of the BRAF gene by Real-Time PCR technique. Kit optimized for Real-Time PCR instrumentation Biorad CFX96 Dx, Biorad Opus Dx, Agilent AriaDx, Hyris bCUBE and Hyris bCUBE3 with Hyris bAPP.

SCIENTIFIC BACKGROUND

Oncogenic BRAF mutations are present in approximately 6% of human cancers and 40-50% of melanomas. BRAF mutations have also been identified in other common cancers, such as colorectal cancer (CRC) and non-small cell lung cancer (NSCLC), albeit at a lower frequency than melanoma (about 10% and 2-5%, respectively).

Other cancer types in which BRAF mutations are relatively common (> 5%) include: thyroid cancer, small bowel cancer, and gastrointestinal neuroendocrine cancer.

§ Classifying BRAF alterations in cancer: new rational therapeutic strategies for actionable mutations. Oncogene. 2018 Mar 15. doi: 10.1038/s41388-018-0171-x. Review.

§ BRAF in non-small cell lung cancer (NSCLC): Pickaxing another brick in the wall. Cancer Treat Rev. 2018 Apr 24;66:82-94. doi: 10.1016/j.ctrv.2018.04.006. Review.

§ Molecular testing for BRAF mutations to inform melanoma treatment decisions: a move toward precision medicine. Mod Pathol. 2018 Jan;31(1):24-38. doi: 10.1038/modpathol.2017.104.

CLINICAL SIGNIFICANCE

The most frequently encountered activating BRAF mutation (approximately 90%) is a point mutation in exon 15 of the gene (c.1799T>A), which causes the substitution of a valine residue in ac. glutamic at codon 600 (V600E) of the protein. This mutation confers two oncogenic properties to the BRAF protein: 1) increases the activity of the BRAF kinase domain (~500-fold compared to the wild-type one), 2) allows BRAF to be active as a monomer when the activity of RAS is reduced, independent of RAS-mediated activation. The result is a hyperfunctioning protein that continuously activates ERK, bypassing RAS activation and ignoring ERK-dependent negative feedback. The molecular characterization of the tumor for the presence/absence of the BRAF mutation is of considerable importance for an adequate therapeutic approach. To date, in fact, two BRAF inhibitors currently used in the treatment of patients with BRAF V600 class I mutations in metastatic melanoma have been approved: vemurafenib and dabrafenib. These inhibitors function as reversible ATP-competitive inhibitors of the BRAF kinase domain.

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ISO 9001:2015
ISO 13485:2016

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DESCRIPTION	LABEL	VOLUME	STORAGE
		ONC-021-25	
Mix oligonucleotides and probes	Mix V600F BRAF 10X	1 x 85 µl	- 20 °C
Buffer and enzyme mix	Mix Real-Time PCR 5X	1 x 170 µl	- 20 °C
Deionized H_20	Deionized H_20	2 x 1 ml	- 20 °C
Genomic DNA or recombinant DNA	Positive control **MUT** V600E BRAF	1 x 22 µl	- 20 °C
Genomic DNA or recombinant DNA	Negative control **WT** V600E BRAF	1 x 22 µl	- 20 °C

TECHNICAL CHARACTERISTICS

COD. ONC-021-25	
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
NEGATIVE 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, Agilent AriaDx, Hyris bCUBE and Hyris bCUBE3 with Hyris bAPP
RUNNING TIME	85 min
THERMAL CYCLING PROFILE	1 cycle at 95 °C (10 min); 50 cycles 95 °C (15 sec) + 60 °C (1 min)
ANALYTICAL SPECIFICITY	Absence of non-specific pairings of oligonucleotides and probes; absence of cross-reactivity
ANALYTICAL SENSITIVITY : LIMIT OF DETECTION (LOD)	≥ 0,025 ng of DNA
ANALYTICAL SENSITIVITY : LIMIT OF BLANK (LOB)	0% NCN
REPRODUCIBILITY	99,9%
DIAGNOSTIC SPECIFICITY / DIAGNOSTIC SENSITIVITY	100%/98%

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