CBFB-MYH11 INV (16) (p13q22) ONE-STEP RT-PCR QUALITATIVE DETECTION

For in vitro diagnostic use

CE IVD

ORDERING INFORMATIONS

REF: ONC-032-25
CND Code: W01060211
RDM Code: 2256822/R
Tests: 25 Reactions: 31 x 3
Manufacturer: BioMol Laboratories s.r.l.

CONTENTS OF THE KIT

The kit consists of: reagents for reverse transcription and Real-Time PCR amplification
**the reagents for RNA extraction are not supplied in the kit.*

PRODUCT CHARACTERISTICS

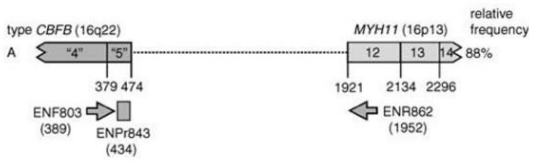
Device belonging to the family of in vitro **REAL-TIME QUALITATIVE PCR-SOMATIC MUTATIONS** medical devices.
Qualitative detection of pericentric inversion INV 16, CBFB-MYH11 and identification of transcripts A, D and E by RT-PCR technique (Reverse transcriptase-polymerase chain reaction) and subsequent detection by PCR-Real-time. Kit optimized for Real-Time PCR instrumentation Biorad CFX96 Dx, Biorad Opus Dx and Agilent AriaDx.

SCIENTIFIC BACKGROUND

Current treatment protocols for acute lymphoblastic leukemia (ALL), acute myeloid leukemia (AML), and chronic myeloid leukemia (CML) are based on prognostic factors, which contribute to therapy stratification. Key prognostic factors identified in leukemia over the years include pretreatment characteristics such as age, WBC count, immunophenotypic profiles, specific chromosomal abnormalities, aberrant fusion genes (FGs), and mutations. In most studies of adult primary AML, the presence of chromosomal abnormalities involving genes encoding central binding factor (CBF) α or β subunits, t(8;21) (q22;q22) or inv(16)(p13q22), respectively, is associated with a very high complete remission rate.

CLINICAL SIGNIFICANCE

In most studies of adult primary AML, the presence of chromosomal abnormalities involving genes encoding central binding factor (CBF) α or β subunits, t(8;21)(q22;q22) or inv(16)(p13q22), respectively, is associated with a very high complete remission rate. At the molecular level, inv(16)(p13q22) results in the fusion gene of CBFβ in chromosomal band 16q22 with the MYH11 gene in chromosomal band 16p13, creating a new chimeric gene, CBFβ/MYH11.4 Since the breakpoints genomes within the CBFβ and MYH11 genes are variable, at least eight different types of CBFβ/MYH11 fusion transcripts are encoded. The most common of these fusion transcripts is referred to as "type A" and is detected in approximately 85% of patients with AML and inv (16) (p13q22).



§ Eur J Haematol 2024 Jun;112(6):964-974. doi: 10.1111/ejh.14192. Epub 2024 Feb 22. Clinical implications of additional chromosomal abnormalities in adult acute myeloid leukemia with inv (16)/t(16;16)/CBFB::MYH11

§ Leukemia. 2003 Dec;17(12):2318-57. doi: 10.1038/sj.leu.2403135. Standardization and quality control studies of 'real-time' quantitative reverse transcriptase polymerase chain reaction of fusion gene transcripts for residual disease detection in leukemia - a Europe Against Cancer program.

§ Kottaridis PD, Gale RE, Frew ME, Harrison G, Langabeer SE, Belton AA et al. The presence of a FLT3 internal tandem duplication in patients with acute myeloid leukemia (AML) adds important prognostic information to cytogenetic risk group and response to the first cycle of chemotherapy: analysis of 854 patients from the United Kingdom Medical Research Council AML 10 and 12 trials. Blood 2001; 98: 1752–1759.

§ Marcucci G, Caligiuri MA, Dohner H, Archer KJ, Schlenk RF, Dohner K et al. Quantification of CBFbeta/MYH11 fusion transcript by real time RT-PCR in patients with INV(16) acute myeloid leukemia. Leukemia 2001; 15: 1072–1080.

§ Appelbaum FR. Perspectives on the future of chronic myeloid leukemia treatment. Semin Hematol 2001; 38: 35–42.

§ Lowenberg B, Downing JR, Burnett A. Acute myeloid leukemia. N Engl J Med 1999; 341: 1051–1062.

§ Grimwade D, Walker H, Oliver F, Wheatley K, Harrison C, Harrison G et al. The importance of diagnostic cytogenetics on outcome in AML: analysis of 1,612 patients entered into the MRC AML 10 trial. The Medical Research Council Adult and Children's Leukaemia Working Parties. Blood 1998; 92: 2322–2333.

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ISO 9001 :2015
ISO 13485:2021

ED.1 REV.0 of 01/10/2024

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DESCRIPTION	LABEL	VOLUME	STORAGE
		ONC-032-25	
Mix oligonucleotides and probes	Mix PCR CBFB MYH11 A 4X	1 x155 µl	- 20 °C
Mix oligonucleotides and probes	Mix PCR CBFB MYH11 D 4X	1 x 155 µl	- 20 °C
Mix oligonucleotides and probes	Mix PCR CBFB MYH11 E 4X	1x 155 µl	- 20 °C
Mix buffer and enzyme RT and Taq polymerase	Mix RT-PCR 4X	1 x 465 µl	- 20 °C
Deionized H_20	Deionized H_20	1 x 1 ml	- 20 °C
Recombinant RNA Positive control	Positive control CBFB MYH11 A, D, E and abl	1 x 90 µl	- 20 °C
Recombinant RNA Negative control	Negative control	1 x 90 µl	- 20 °C

TECHNICAL CHARACTERISTICS

COD. ONC-032-25

STABILITY	18 months
REAGENTS STATUS	Ready to use
BIOLOGICAL MATRIX	Total RNA extracted from white blood cells from whole blood or bone marrow aspirate.
CONTROLS	Recombinant RNA for at least 3 analytical sessions; single positive control for CBFB/MYH11 A, D, E negative control for abl
TECHNOLOGY	RT-PCR ONE STEP in Real-time; oligonucleotides and specific probes for the translocation and for the ABL gene; 2 FAM/HEX fluorescence channels
VALIDATED INSTRUMENTS	Biorad CFX96 Dx, Biorad Opus Dx and Agilent AriaDx
RUNNING TIME	100 min
THERMAL CYCLING PROFILE	1 cycle at 50 °C (25 min); 1 cycle at 95 °C (2 min); 45 cycles at 95 °C (5 sec) + 60 °C (45 sec)
ANALYTICAL SPECIFICITY	Absence of non-specific pairings of oligonucleotides and probes; absence of cross-reactivity
LIMIT OF DETECTION (LOD)	≥ 0,025 ng of RNA; ≥1%
LIMIT OF BLANK (LOB)	0% NCN
REPRODUCIBILITY	99,9%
DIAGNOSTIC SPECIFICITY / DIAGNOSTIC SENSITIVITY	100%/98%

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