PML-RARA t (15; 17) (q22; q21) ONE-STEP RT-PCR QUALITATIVE DETECTION (bcr1, bcr2, bcr3)

For in vitro diagnostic use

CE IVD

ORDERING INFORMATIONS

REF: ONC-030-25
CND Code: W01060299
RDM Code: 2256789/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

Qualitative detection of PML-RARA t(15;17) translocation by RT-PCR technique (Reverse transcriptase-polymerase chain reaction) and subsequent detection in Real-time-PCR. 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

PML-RARA transcripts derive from the t (15; 17) (q22; q21) translocation and are associated with most cases of acute promyelocytic leukemia (APL).

The two genes fused in the t (15; 17) translocation are the PML (Promyelocytic leukemia) gene, located on chromosome 15, and the retinoic acid receptor α (RARA) gene located on chromosome 17. The chimeric protein PML-RARA it is a transcriptional repressor. In the absence of the ligand (retinoic acid, RA), it binds to DNA together with the co-repressors SMRT (silencing mediator for RAR and TR) and N-CoR (nuclear receptor corepressor) making chromatin inaccessible to transcriptional activators or various machinery for basal transcription.

§ Longo L, Pandolfi PP, Biondi A, Rambaldi A, Mencarelli A, Lo Coco F et al. Rearrangements and aberrant expression of the retinoic acid receptor alpha gene in acute promyelocytic leukemias. J Exp Med 1990; 172: 1571–1575.

§ Lemons RS, Eilender D, Waldmann RA, Rebentisch M, Frej AK,Ledbetter DH et al. Cloning and characterization of the t(15;17) translocation breakpoint region in acute promyelocytic leukemia. Genes Chromosomes Cancer 1990; 2: 79–87.

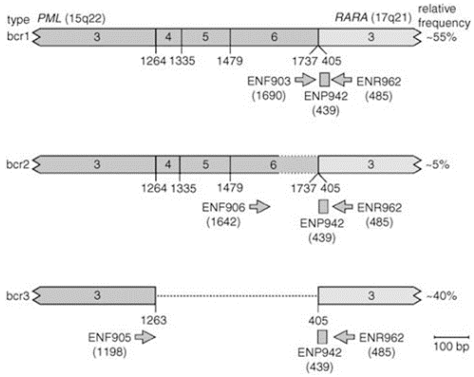
§ Zelent A, Guidez F, Melnick A, Waxman S, Licht JD. Translocations of the RARalpha gene in acute promyelocytic leukemia. Oncogene 2001; 20: 7186–7203.

§ Grimwade D. The pathogenesis of acute promyelocytic leukaemia: evaluation of the role of molecular diagnosis and monitoring in the management of the disease. Br J Haematol 1999; 106: 591–613.

§ Reiter A, Saubele S, Grimwade D, Wiesmels JL, Segal M, Lafage-Pochitaloff M et al. Genomic anatomy of the reciprocal translocation t(15;17) in acute promyelocytic leukemia. Gene Chromosome Cancer 2003; 36: 175–188.

CLINICAL SIGNIFICANCE

RARA breakpoints always occur in intron 2 which is 17 kb long while for the PML locus, in the t(15;17) translocation breakpoints three regions are involved: intron 6 (bcr1; 55% of cases) , exon 6 (bcr2; 5% of cases) and intron 3 (bcr3; 40% of cases). As a result, therefore, there are three possible PML-RARA isoforms: the long isoform L (bcr1), the variant isoform V (bcr2), and the short isoform S (bcr3).



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ISO 9001:2015
ISO 13485:2016

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DESCRIPTION	LABEL	VOLUME	STORAGE
		ONC-030-25	
Mix oligonucleotides and probes	Mix PCR PML-RARA bcr1 2X	1 x 350 µl	- 20 °C
Mix oligonucleotides and probes	Mix PCR PML-RARA bcr2 2X	1 x 350 µl	- 20 °C
Mix oligonucleotides and probes	Mix PCR PML-RARA bcr3 2X	1 x 350 µl	- 20 °C
Mix buffer and Taq-polymerase	Mix RT-PCR 4X	1 x 480 µl	- 20 °C
Deionized H_20	Deionized H_20	2 x 1 ml	- 20 °C
Recombinant RNA	Positive control bcr1 - bcr2- bcr3- abl	1 x 70 µl	- 20 °C
Recombinant RNA	Negative control	1 x 70 µl	- 20 °C

TECHNICAL CHARACTERISTICS

COD. ONC-030-25	
STABILITY	18 months
REAGENTS STATUS	Ready to use
BIOLOGICAL MATRIX	Total RNA extracted from white blood cells from whole blood or bone marrow aspirate.
POSITIVE CONTROL	Recombinant RNA for at least 3 analytical sessions; single positive control for bcr1, bcr2, bcr3; negative control for abl
TECHNOLOGY	RT-PCR ONE STEP in Real-time; 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	75 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
ANALYTICAL SENSITIVITY : LIMIT OF DETECTION (LOD)	≥ 0,025 ng of RNA
ANALYTICAL SENSITIVITY : LIMIT OF BLANK (LOB)	0% NCN
REPRODUCIBILITY	99,9%
DIAGNOSTIC SPECIFICITY / DIAGNOSTIC SENSITIVITY	100%/98%

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