

# BCR-ABL1 t (9;22) ONE-STEP RT-PCR QUALITATIVE DETERMINATION (p210, p190, p230)

## ORDERING INFORMATIONS

REF: *ONC-010-25*  
 CND Code: *W01060208*  
 RDM Code: *2079229/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.*

For in vitro diagnostic use



## PRODUCT CHARACTERISTICS

Qualitative analysis of t(9;22) BCR-ABL1 translocation by RT-PCR technique (Reverse transcriptase-polymerase chain reaction) and subsequent detection in Real-time-PCR. Optimized kit for Real-Time PCR instrumentation Biorad CFX96 Dx, Biorad Opus Dx, Agilent AriaDx, Hyris bCUBE and Hyris bCUBE3 with Hyris bAPP.

## SCIENTIFIC BACKGROUND

Myeloproliferative neoplasms (MPNs) are hematologic malignancies characterized by the proliferation of one or more myeloid lineages: granulocytic, erythroid, megakaryocytic, and/or mast cell. According to the 2016 World Health Organization criteria, the MPN classification includes seven subcategories: chronic myeloid leukemia (CML), chronic neutrophilic leukemia, polycythemia vera (PV), primary myelofibrosis (PMF), essential thrombocythemia (ET), eosinophilic leukemia chronic - not otherwise specified and MPN, unclassifiable (MPN-U).

The Philadelphia chromosome (Ph) derived from the translocation between chromosomes 9 and 22 with subsequent BCR-ABL1 fusion, is present in about 95% of cases of chronic myeloid leukemia (CML), in 25-30% of cases of acute lymphoblastic leukemia (ALL) of adults and in 2-4% of ALL of children.

§ Genetic basis and molecular pathophysiology of classical myeloproliferative neoplasms. *Blood*. 2017 Feb 9;129(6):667-679. doi: 10.1182/blood-2016-10-695940. Epub 2016 Dec 27. Review.

§ Classification and diagnosis of myeloproliferative neoplasms: the 2008 World Health Organization criteria and point-of-care diagnostic algorithms. *Leukemia*. 2008 Jan;22(1):14-22. Epub 2007 Sep 20. Review.

§ The 2016 revision to the World Health Organization classification of myeloid neoplasms and acute leukemia. *Blood*. 2016 May 19;127(20): 2391-405. Epub 2016 Apr 11.

§ Guidelines for the measurement of BCR-ABL1 transcripts in chronic myeloid leukaemia. *Br J Haematol*. 2011 Apr;153(2):179-90. doi: 10.1111/j.1365-2141.2011.08603.x. Epub 2011 Mar 8.

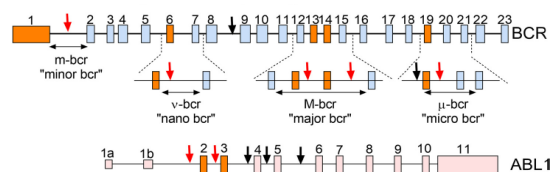
§ European LeukemiaNet (2009). Chronic myeloid leukemia: an update of concepts and management recommendations of European LeukemiaNet. *Journal of Clinical Oncology*, 27, 6041-6051.

## CLINICAL SIGNIFICANCE

The BCR-ABL1 rearrangement results in the generation of fusion proteins with constitutive tyrosine kinase activity. Based on the specific breakpoints of the rearrangement, different isoforms of the BCR-ABL1 fusion protein are generated, which correlate with different leukemic phenotypes.

Three breakpoint regions in the BCR gene have been described: major (M-BCR), minor (m-BCR), and micro ( $\mu$ BCR). More than 95% of Ph<sup>+</sup> CML patients have the rearrangement in the M-BCR region (p210 BCR-ABL1), with the e13a2 and e14a2 transcripts most represented.

The breakpoint in the m-BCR region generates the p190 BCR-ABL1 protein with the e1a2 transcript mostly represented. A third BCR-ABL1 protein, p230BCR-ABL1, can also be observed.



# BCR-ABL1 t (9; 22) ONE-STEP RT-PCR QUALITATIVE DETECTION (p210, p190, p230)

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DESCRIPTION	LABEL	VOLUME	STORAGE
		<b>ONC-010-25</b>	
Mix oligonucleotides and probes	Mix PCR p210 BCR-ABL1 2X	350 µl	- 20 °C
Mix oligonucleotides and probes	Mix PCR p190 BCR-ABL1 2X	350 µl	- 20 °C
Mix oligonucleotides and probes	Mix PCR p230 BCR-ABL1 2X	350 µl	- 20 °C
Mix buffer and RT enzyme and Taq-polymerase	Mix RT-PCR 4X	480 µl	- 20 °C
Deionized H <sub>2</sub> O	Deionized H <sub>2</sub> O	2 x 1 ml	- 20 °C
Recombinant RNA	Positive control p190/p210/p230-abl	70 µl	- 20 °C
Recombinant RNA	Negative control housekeeping	70 µl	- 20 °C

## TECHNICAL CHARACTERISTICS

COD. ONC-010-25

STABILITY	18 months
REAGENTS STATUS	Ready to use
POSITIVE CONTROL	Total RNA extracted from white blood cells from whole blood or bone marrow aspirate.
BIOLOGICAL MATRIX	Recombinant RNA for at least 3 analytical sessions; single positive control for p190/p210/p230 and abl; 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, Agilent AriaDx, Hyris b-CUBE and Hyris b-CUBE3 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%