BCR-ABL1 t (9; 22) ONE-STEP RT-PCR QUANTITATIVE DETECTION p210 (M-BCR b3a2 e b2a2)

For in vitro diagnostic use

CE IVD

ORDERING INFORMATIONS

REF: ONC-015-25
CND Code: W01060208– T(9;22)
RDM Code: 2259479/R
Tests: 25
Reactions: 50
Manufacturer: BioMol Laboratories s.r.l.

CONTENTS OF THE KIT

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

PRODUCT CHARACTERISTICS

Quantitative analysis of t (9; 22) translocation BCR-ABL1 breakpoint M-bcr (p190, b3a2 e b2a2 transcripts) by RT-PCR (Reverse transcriptase-polymerase chain reaction) and subsequent detection with qPCR-Real-time using ERM-AD623 for standard curve, produced and certified in accordance with the guidelines of the European Reference Materials. Kit optimized for Real-Time PCR instrumentation Biorad CFX96 Dx, Biorad Opus Dx, Agilent AriaDx,

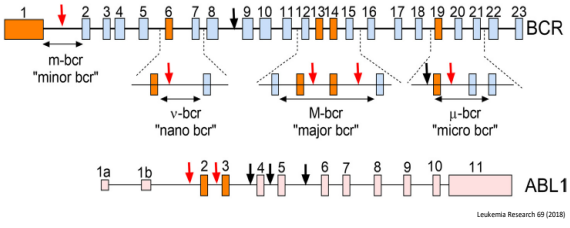
SCIENTIFIC BACKGROUND

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.

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 (µ-BCR). More than 95% of Ph+ 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, p230 BCR-ABL1 (µBCR), can also be observed. This translocation is associated with CML characterized by granulocytic hyperplasia and, in general, with a more indolent clinical course.



§ 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.

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ISO 9001:2015
ISO 13485:2016

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DESCRIPTION	LABEL	VOLUME	STORAGE
		ONC-015-25	
Mix oligonucleotides and probes	Mix PCR p210 BCR-ABL1 2X	550 µl	- 20 °C
Mix buffer and RT/Taq polymerase enzyme	Mix RT-PCR 4X	275 µl	- 20 °C
Deionized H_20	Deionized H_20	1 ml	- 20 °C
Recombinant DNA	CAL 1 p210/abl – $1,08^6$ copies	20 µl	- 20 °C
Recombinant DNA	CAL 2 p210/abl -$1,08^5$ copies	20 µl	- 20 °C
Recombinant DNA	CAL 3 p210/abl -$1,08^4$ copies	20 µl	- 20 °C
Recombinant DNA	CAL 4 p210/abl - $1,08^3$ copies	20 µl	- 20 °C
Recombinant DNA	CAL 5 p210/abl - $1,08^2$ copies	20 µl	- 20 °C
Recombinant DNA	CAL 6 p210/abl abl - 10 copies	20 µl	- 20 °C
Recombinant RNA	Positive control p210/abl	20 µl	- 20 °C
Recombinant RNA	Negative control abl	20 µl	- 20 °C

TECHNICAL CHARACTERISTICS

COD. ONC-015-25

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 AND NEGATIVE CONTROL	Recombinant RNA for at least 3 analytical sessions
STANDARD CURVE	Recombinant DNA p210, 6 points with known concentration from 10 to 10^6 copies, (ERM-AD623 for standard curve, produced and certified in accordance with the guidelines of the European Reference Materials)
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 e Agilent AriaDx
RUNNING TIME	85 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). Reading at 60 °C
ANALYTICAL SPECIFICITY	Absence of non-specific pairings of oligonucleotides and probes; absence of cross-reactivity
ANALYTICAL SENSITIVITY : LIMIT OF DETECTION (LOD)	= 10 copies
ANALYTICAL SENSITIVITY : LIMIT OF BLANK (LOB)	0% NCN
REPRODUCIBILITY	99,9%
DIAGNOSTIC SPECIFICITY / DIAGNOSTIC SENSITIVITY	100%/98%

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