BCR-ABL1 t(9;22) (mBCR and µBCR) QUANTITATIVE DETECTION p190/p230

For in vitro diagnostic use

CE IVD

ORDERING INFORMATIONS

REF: ONC-016-25
CND Code: W01060208– t (9;22)
RDM Code: 1822476/R
Tests: 25
Reactions: 50 x 2
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

Device belonging to the family of in vitro medical devices **REAL-TIME QUANTITATIVE PCR-SOMATIC MUTATIONS**. Quantitative detection of BCR-ABL1 t (9;22) breakpoint **m-bcr (e1a3 e e1a2)** and **µ-bcr (e18a2, e18a3, e19a2 e e19a3)** transcripts by reverse transcription, amplification with oligonucleotides and specific probes and subsequent detection with qPCR-Real-time using plasmids for standard curve. Kit optimized for Real-Time PCR instrumentation Biorad CFX96 Dx, Biorad Opus Dx, Agilent AriaDx.

SCIENTIFIC BACKGROUND

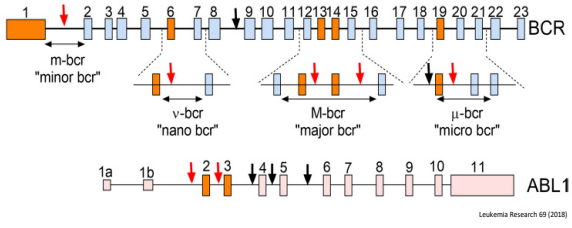
Myeloproliferative neoplasms (MPNs) are hematologic malignancies characterized by the proliferation of one or more myeloid lineages: granulocytic, erythroid, megakaryocytic, and/or mast cell. According to the 2016 World Health Organization criteria, the MPN classification includes seven subcategories: 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.

§ 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.
§ 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.
§ J Clin Oncol. 2009 Dec 10;27(35):6041-51. doi: 10.1200/JCO.2009.25.0779. Epub 2009 Nov 2. Chronic myeloid leukemia: an update of concepts and management recommendations of European LeukemiaNet
§ Leukemia. 2009 Nov;23(11):1957-63. doi: 10.1038/leu.2009.168. Epub 2009 Aug 27. Harmonization of molecular monitoring of CML therapy in Europe
§ European LeukemiaNet (2009). Chronic myeloid leukemia: an update of concepts and management recommendations of European LeukemiaNet. Journal of Clinical Oncology, 27, 6041–6051.
§ Leukemia. 2015 May;29(5):999-1003. doi: 10.1038/leu.2015.29. Epub 2015 Feb 5. Laboratory recommendations for scoring deep molecular responses following treatment for chronic myeloid leukemia

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.



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ISO 9001 :2015
ISO 13485:2021

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

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Reactions: 100
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CONTENTS OF THE KIT

DESCRIPTION	LABEL	LABEL	VOLUME	STORAGE
			ONC-016-25	
Mix oligonucleotides and probes	Mix PCR p190 BCR-ABL1 4X		1 x 250 µl	- 20 °C
Mix oligonucleotides and probes	Mix PCR p230 BCR-ABL1 4X		1 x 250 µl	- 20 °C
Mix buffer and RT/Taq polymerase enzyme	Mix RT-PCR 4X		1 x 500 µl	- 20 °C
Deionized H_20	Deionized H_20		1 x 1 ml	- 20 °C
Recombinant DNA	CAL 1 p190/abl – 1,08 x10^5 copies	CAL 1 p230/abl – 1,08 x10^5 copies	1 x 30 µl	- 20 °C
Recombinant DNA	CAL 2 p190/abl -1,08 x10^4 copies	CAL 2 p230/abl -1,08 x10^4 copies	1 x 30 µl	- 20 °C
Recombinant DNA	CAL 3 p190/abl -1,08 x10^3 copies	CAL 3 p230/abl -1,08 x10^3 copies	1 x 30 µl	- 20 °C
Recombinant DNA	CAL 4 p190/abl - 1,08 x10^2 copies	CAL 4 p230/abl - 1,08 x10^2 copies	1 x 30 µl	- 20 °C
Recombinant DNA	CAL 5 p190/abl – 10,8 copies	CAL 5 p230/abl – 10,8 copies	1 x 30 µl	- 20 °C
Recombinant RNA	Positive control p190/p230/abl		1 x 60 µl	- 20 °C
Recombinant RNA	Negative control housekeeping		1 x 60 µl	- 20 °C

TECHNICAL CHARACTERISTICS

COD. ONC-016-25

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 CONTROLS	Recombinant RNA for 3 analytical sessions
STANDARD CURVE	Recombinant DNA p190 and p230, 5 points with known concentration from 10,8 to 1,085 copies, plasmid standard curve
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 and Agilent AriaDx
RUNNING TIME	110 min
THERMAL CYCLING PROFILE	1 cycle at 25 °C (2 min); 1 cycle at 50 °C (25 min); 1 cycle at 95 °C (2 min); 50 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
LIMIT OF DETECTION (LOD)	= 10 copies
LIMIT OF BLANK (LOB)	0% NCN
REPRODUCIBILITY	99,9%
DIAGNOSTIC SPECIFICITY / DIAGNOSTIC SENSITIVITY	100%/98%

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