AML1-ETO t (8; 21) (Q22; Q22) ONE-STEP RT-PCR QUALITATIVE DETECTION

For in vitro diagnostic use

CE IVD

ORDERING INFORMATIONS

REF: ONC-031-25
CND Code: W01060299
RDM Code: 2256801/R
Tests: 25 Reactions: 31
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

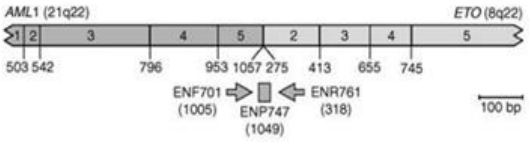
Device belonging to the family of in vitro **REAL-TIME QUALITATIVE PCR-SOMATIC MUTATIONS** medical devices.
Qualitative detection of AML1-ETO t(8;21) translocation by RT-PCR technique (Reverse transcriptase-polymerase chain reaction) and subsequent detection in Real-time-PCR. Kit optimized for Real-Time PCR instrumentation Biorad CFX96 Dx, Biorad Opus Dx 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. The AML1/ETO fusion transcript is expressed in all patients with acute myeloid leukemia (AML) t (8; 21) (q22; q22).

CLINICAL SIGNIFICANCE

The translocation between chromosomes 8 and 21, t(8;21) (q22; q22), is one of the most frequent recurrent cytogenetic abnormalities in acute myeloid leukemia (AML). The t(8;21) causes the fusion of the AML1 gene on chromosome 21 with the ETO gene on chromosome 8. The new chimeric gene (AML1/ETO) produces a transcript that appears to be important for maintaining the leukemic phenotype in leukemic cell lines. It is associated with a good response to chemotherapy, with a high rate of remission and survival.



Identification scheme of the three AML1/ETO translocation points through the different combination of primers. (*Leukemia. Blood 1996;88:2183–2191.*)

§ 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.

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

§ 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.

§ 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.

§ Jurlander J, Caligiuri MA, Ruutu T, Baer MR, Strout MP, Oberkircher AR et al. Persistence of the AML1/ETO fusion transcript in patients treated with allogeneic bone marrow transplantation for t(8;21) leukemia. Blood 1996; 88: 2183–2191.

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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-031-25	
Mix oligonucleotides and probes	Mix PCR AML1-ETO 4X	1 x 155 µl	- 20 °C
Mix buffer and enzyme RT and Taq polymerase	Mix RT-PCR 4X	1 x 155 µl	- 20 °C
Deionized H_20	Deionized H_20	1 x 1 ml	- 20 °C
Recombinant RNA Positive control	Positive control AML1-ETO-abl	1 x 30 µl	- 20 °C
Recombinant RNA Negative control	Negative control	1 x 30 µl	- 20 °C

TECHNICAL CHARACTERISTICS

COD. ONC-031-25

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; positive control and negative control.
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	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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