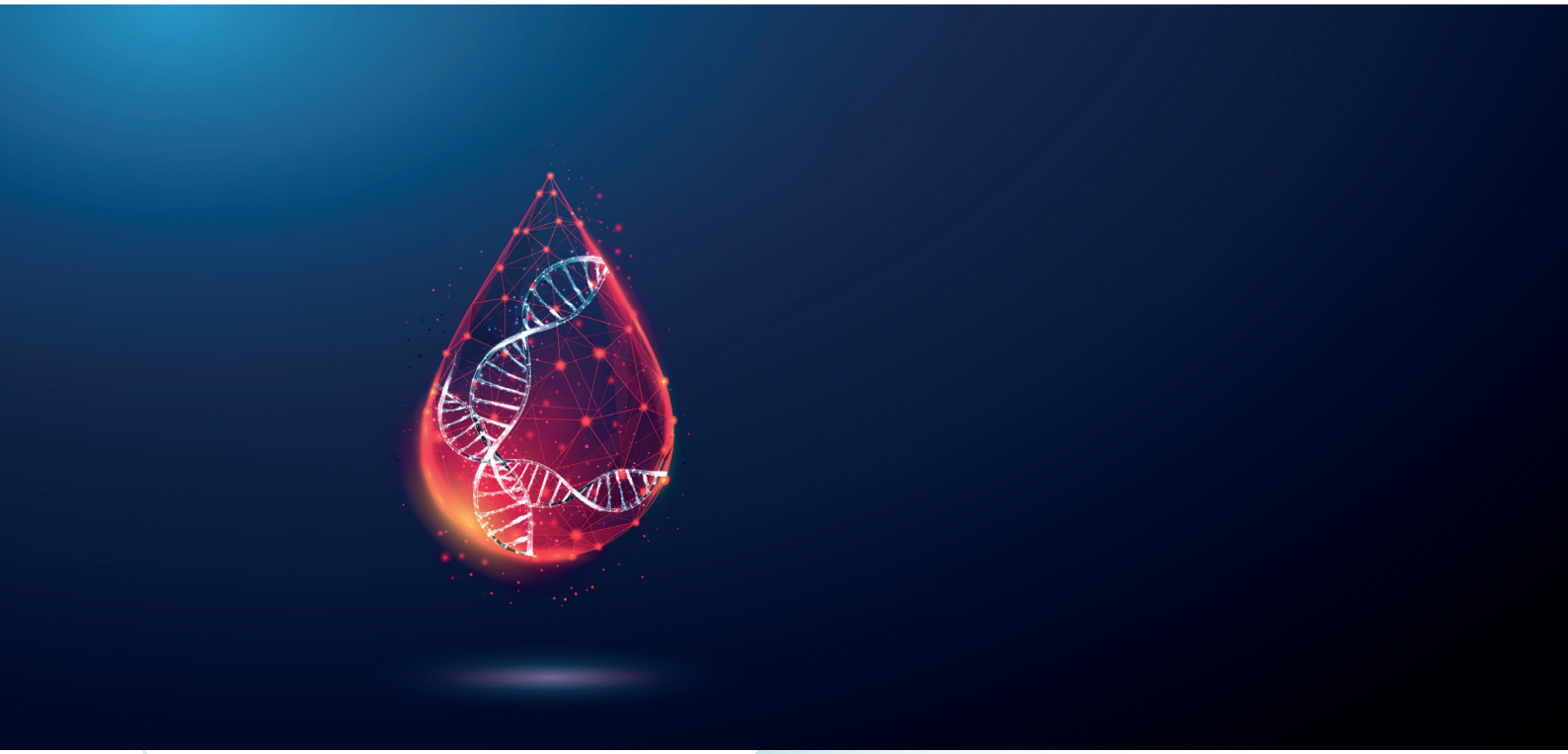
REALQUALITY ONCOHEMATOLOGY

Kits for the detection of most important oncohematology traslocations by One-Step Real-Time RT PCR



- BCR-ABL p210
- BCR-ABL p190
- PML-RARa bcr1
- PML-RARa bcr2
- PML-RARa bcr3
- AML1-ETO
- CBFβ-MYH11 (INV 16)
- WT 1

Real-Time PCR

CE IVD

Developed in accordance with Europe Against Cancer (EAC) Guidelines – Leukemia 2003

AB
ANALITICA
ADVANCED BIOMEDICINE

BCR-ABL Translocations in chronic myeloid leukemia (CML)

BCR-ABL p210

REALQUALITY
▸ RQ-BCR-ABL p210 One-Step
(ref. RQ-105)

CE IVD

DESCRIPTION:
REALQUALITY RQ-BCR-ABL p210 One-Step is a CE-IVD kit for the identification and quantification of the t(9;22) (q34;q11) translocation, in the variant p210 (M-bcr b3a2 and b2a2 transcripts), which involves the ABL proto-oncogene on chromosome 9 and part of the BCR gene on chromosome 22. The test is based on reverse transcription and Real-Time PCR in a single step.

The device was developed in accordance with the Europe Against Cancer (EAC) guidelines, validated using the "Raccomandazioni e Indicazioni Laboratoristiche" of the LabNet network., approved for use in the LabNet network.

PRODUCT CHARACTERISTICS:
- The device is validated on RNA extracted from leukocyte pellet.
- Requires 5 µL of extracted RNA/reaction at the concentration of 40ng/µL.
- Includes dUTP/UNG system for contamination prevention and a fluorescence normalizer.
- The test allows the quantification of the M-bcr transcripts if used in combination with the **REALQUALITY RQ-BCR-ABL p210 STANDARD** for monitoring the Minimal Residual Disease (MRD).
- The device allows the experssion of results in International Scale (IS), if used in combination with **BCR-ABL p210 REFERENCE**.
- The test is based on reverse transcription and Real-Time PCR in a single step.
- The assay shares the same thermal profile of the **REALQUALITY RQ-BCR-ABL p190 One-Step** kit.
- Validated on the most common Real-Time PCR thermocyclers.

KIT CONTENT:
- Ready-to-use reagents for Reaverse Transcrition and Real-Time PCR.
- Positive control (DNA containing parts of the BCR-ABL p210 and ABL sequences).

BCR-ABL Translocations in chronic myeloid leukemia (CML)

BCR-ABL p210

REALQUALITY
▸ RQ-BCR-ABL p210 STANDARD
(ref. RQ-54-SM)

CE IVD

DESCRIPTION:

Ready-to-use single-plasmid standards for quantification of the transcripts of BCR-ABL p210 (M-bcr), ABL and GUSB.

The product has been validated for use with the kit REALQUALITY RQ-BCR-ABL p210 One-Step.

PRODUCT CHARACTERISTICS:

- Standards calibrated with **IRMM ERM-AD623 BCR-ABL1** (certified reference material of known titer). Single plasmid standards containing 2 specific fragments from BCR-ABL p210 and ABL sequences.

KIT CONTENT:

- 6 standard points with concentrations ranging from 10^1 to 10^6 copies/reaction.
- The provided volume is sufficient for 6 standard curves.

▸ p210 RNA REFERENCE
(ref. RQ-185-SM)

CE IVD

DESCRIPTION:

RNA reference for molecular assays for detection and/or quantification of BCR-ABL p210 transcript.

PRODUCT CHARACTERISTICS:

- Reference calibrated with "**1st World Health Organization (WHO) International Genetic Reference Panel for quantitation of BCR-ABL translocation by RQ-PCR (NIBSC, UK, Cod: 09/138)**".

KIT CONTENT:

- 5 different mixes of total RNA from a cell line carrying the BCR-ABL t(9:22) p210 b3a2 translocation and a cell line not carrying the translocation with percentages of BCR-ABL p210 transcript close to 10%, 1%, 0.1%, 0.01% and 0.0032% respectively.

BCR-ABL Translocations in chronic and acute myeloid leukemia (CML, AML)

BCR-ABL p190

REALQUALITY
▸ RQ-BCR-ABL p190 One-Step
(ref. RQ-115)

CE IVD

DESCRIPTION:

REALQUALITY RQ-BCR-ABL p190 One-Step is a CE-IVD kit for the identification and quantification of the translocation t(9;22) (q34;q11), in the variant p190 (m-bcr e1a2 transcript), which involves the ABL proto-oncogene on chromosome 9 and part of the BCR gene on chromosome 22. The RNA of the BCR-ABL fusion gene are detected by one-step Real-time RT-PCR.

The device was developed in accordance with the Europe Against Cancer (EAC) guidelines.

PRODUCT CHARACTERISTICS:

- The device is validated on RNA extracted from leukocyte pellet.
- Requires 5 µL of extracted RNA/reaction at the concentration of 40ng/µL.
- Includes dUTP/UNG system for contamination prevention and a fluorescence normalizer.
- The test allows the quantification of the m-bcr transcripts if used in combination with the **REALQUALITY RQ-BCR-ABL p190 STANDARD**.
- Real-time reverse transcription and amplification take place in a single step (Real-Time RT-PCR).
- The assay shares the same thermal profile of the **REALQUALITY RQ-BCR-ABL p210 One-Step** kit.
- Validated on the most common Real-Time PCR thermocyclers.

KIT CONTENT:

- Ready-to-use reagents for Real time amplification.
- Positive control (DNA containing parts of the BCR-ABL p190 and ABL sequences).

BCR-ABL Translocations in chronic and acute myeloid leukemia (CML, AML)

BCR-ABL p190

REALQUALITY
▸ RQ-BCR-ABL p190 STANDARD
(ref. RQ-116)

CE IVD

DESCRIPTION:

Ready-to-use quantification standards for quantification of BCR-ABL m-bcr (p190) and ABL gene transcripts.

The product has been validated for use with the kit REALQUALITY RQ-BCR-ABL p190 One-Step.

PRODUCT CHARACTERISTICS:

- Standards calibrated by verifying the ABL target with **IRMM ERM-AD623 BCR-ABL1** (certified plasmid DNA reference)

KIT CONTENT:

- Quantification standards: DNA containing 2 specific cDNA fragments derived from BCR-ABL p190 and ABL transcripts.
- 5 standard points with concentrations ranging from 10^2 to 10^6 copies/reaction.
- The provided volume is sufficient for 6 standard curves.

PML-RARa translocations in Acute Promyelocytic Leukemia (APL) and Acute Myeloid Leukemia (AML)

PML-RARa bcr1, bcr2 and bcr3

REALQUALITY

- **RQ-PML-RARa bcr 1 One-Step** (ref. RQ-179)
- **RQ-PML-RARa bcr 2 One-Step** (ref. RQ-181)
- **RQ-PML-RARa bcr 3 One-Step** (ref. RQ-183)

CE IVD

DESCRIPTION:

REALQUALITY RQ-PML-RARa One-Step are CE-IVD kits for the identification and quantification of the bcr1, bcr2 and bcr3 variants of the PML-RARa fusion transcript resulting from the translocation t(15;17)(q22;q21) involving the PML gene on chromosome 15 and the RARa gene on chromosome 17, by one-step Real-time RT-PCR.

The products have been validated for use with the kit REALQUALITY RQ-PML-RARa bcr1, bcr2 and bcr3 STANDARD.

PRODUCT CHARACTERISTICS:

- The device are validated on RNA extracted from leukocyte pellet.
- Requires 5 µL of extracted RNA/reaction at the concentration of 40ng/µL.
- Includes dUTP/UNG system for contamination prevention and a fluorescence normalizer.
- The tests allow the quantification of the PML-RARa bcr1, PML-RARa bcr2, PML-RARa bcr3 transcripts if used in combination with the REALQUALITY RQ-PML-RARa STANDARDS (**REALQUALITY RQ-PML-RARa bcr1 STANDARD, REALQUALITY RQ-PML-RARa bcr2 STANDARD, REALQUALITY RQ-PML-RARa bcr3 STANDARD**), the assays allow the absolute quantification of the number of PML-RARa bcr transcripts present in the test sample, normalized to the number of transcripts of the housekeeping ABL gene.
- ABL reference gene for the normalization of the quantitative results.
- Real-time reverse transcription and amplification take place in a single step (Real-Time RT-PCR).
- Validated on the most common Real-Time PCR thermocyclers.

KIT CONTENT:

- Ready-to-use reagents for Real-Time PCR amplification.
- Positive control (single plasmid containing 2 cDNA fragments for PML-RARa specific variants and ABL targets).

PML-RARa translocations in Acute Promyelocytic Leukemia (APL) and Acute Myeloid Leukemia (AML)

PML-RARa bcr1, bcr2 and bcr3

REALQUALITY

- **RQ-PML-RARa bcr 1 STANDARD** (ref. RQ-179)
- **RQ-PML-RARa bcr 2 STANDARD** (ref. RQ-181)
- **RQ-PML-RARa bcr 3 STANDARD** (ref. RQ-183)

CE IVD

DESCRIPTION:

Ready-to-use single-plasmid standards for quantification of RQ-PML-RARa bcr1, bcr2 and bcr3 variants and ABL gene transcripts.

The products have been validated for use with the kit REALQUALITY RQ-PML-RARa bcr1 One-Step, REALQUALITY RQ-PML-RARa bcr2 One-Step, REALQUALITY RQ-PML-RARa bcr3 One-Step.

PRODUCT CHARACTERISTICS:

- Standards calibrated with **IRMM ERM-AD623 BCR-ABL1** (certified plasmid DNA reference).

KIT CONTENT:

- Quantification standards: DNA containing 2 specific cDNA fragments derived from *PML-RARa variants and ABL*.
- 5 standard points with concentrations ranging from 10^2 to 10^6 copies/reaction.
- The provided volume is sufficient for 6 standard curves.

AML1-ETO translocations in Acute Myeloid Leukemia (AML)

AML1-ETO

REALQUALITY
▸ RS-AML1-ETO
(ref. RQ-S59)

DESCRIPTION:
REALQUALITY RS-AML1-ETO is a CE-IVD kit for the identification and quantification of the translocation t(8;21)(q22;q22), which involves the AML1 gene in chromosome region 21q22 and the ETO gene in chromosome region 8q22. The RNA of the AML1-ETO fusion gene are detected by Real-time PCR.

PRODUCT CHARACTERISTICS:
- The device is validated on cDNA derived from RNA of leucocyte pellet.
- Requires 5 µL of extracted cDNA/reaction derived to 1 µg of total RNA.
- Includes dUTP/UNG system for contamination prevention and a fluorescence normalizer.
- The test allows the quantification of the AML1-ETO transcripts if used in combination with **REALQUALITY RQ-AML1-ETO STANDARD**.
- The assay shares the same thermal profile of the **REALQUALITY RS-INV 16 and RS-WT1** kits.
- Validated on the most common Real-Time PCR thermocyclers.

KIT CONTENT:
- Ready-to-use reagents for Real-Time PCR amplification.
- Positive control AML1-ETO (DNA containing parts AML1-ETO sequences).
- Positive control ABL (DNA containing parts ABL sequences).

REALQUALITY
▸ RQ-AML1-ETO STANDARD
(ref. RQ-60)

DESCRIPTION:
Ready-to-use quantification standards for quantification of AML1-ETO and ABL gene transcripts.

The product has been validated for use with the kit REALQUALITY RS-AML1-ETO.

KIT CONTENT:
- Quantification standards: DNA containing cDNA fragments derived from AML1-ETO and ABL transcripts.
- 5 standard points with concentrations ranging from 10^2 to 10^5 copies/reaction.
- The provided volume is sufficient for 10 standard curves.

CBFβ-MYH11 translocations in Acute Myeloid Leukemia (AML)

CBFβ-MYH11 (INV 16)

REALQUALITY
▸ RS-INV 16
(ref. RQ-S61)

DESCRIPTION:
REALQUALITY RS-INV 16 is a CE-IVD kit for the identification and quantification of the fusion transcript resulting from the pericentric inversion of chromosome 16, inv(16)(p13;q22) which involves the CBFβ gene in chromosome region 16q22 and MYH11 gene in chromosome region 16p13. The RNA of the INV 16 fusion gene are detected by Real-time PCR.

PRODUCT CHARACTERISTICS:
- The device is validated on RNA extracted from leukocyte pellet.
- Requires 5 µL of extracted cDNA/reaction derived to 1 µg retrotrascripted RNA.
- Includes dUTP/UNG system for contamination prevention and a fluorescence normalizer.
- The test allows the quantification of the INV 16 transcripts if used in combination with **REALQUALITY RQ-INV 16 STANDARD**.
- The assay shares the same thermal profile of the **REALQUALITY RS-AML1-ETO** and **RS-WT1** kits.
- Validated on the most common Real-Time PCR thermocyclers.

KIT CONTENT:
- Ready-to-use reagents for Real-Time PCR amplification.
- Positive control INV 16 (DNA containing parts INV 16 sequences).
- Positive control ABL (DNA containing parts ABL sequences).

REALQUALITY
▸ RQ-INV 16 STANDARD
(ref. RQ-62)

DESCRIPTION:
Ready-to-use quantification standards for quantification of INV 16 and ABL gene transcripts.

The product has been validated for use with the kit REALQUALITY RS-INV 16.

KIT CONTENT:
- Quantification standards: DNA containing cDNA fragments derived from INV 16 and ABL transcripts.
- 5 standard points with concentrations ranging from 10^2 to 10^5 copies/reaction.
- The provided volume is sufficient for 10 standard curves.

Wilms Tumor 1 gene (WT 1) expression in Acute Myeloid Leukemia (AML)

Wilms Tumor 1 gene (WT 1)

REALQUALITY
▸ RS-WT-1
(ref. RQ-S57)

CE IVD

DESCRIPTION:

REALQUALITY RS-WT-1 is a CE-IVD kit for the quantification and the expression Wilms Tumor 1 gene (WT 1), located in chromosome region 11p13. The test is based on amplification of cDNA corresponding to a fragment spanning the junction of exons 1 and 2 detected by Real-time PCR.

PRODUCT CHARACTERISTICS:

- The device is validated on RNA extracted from leukocyte pellet.
- Requires 5 µL of extracted cDNA/reaction derived to 1 µg retrotrascripted RNA.
- Includes dUTP/UNG system for contamination prevention and a fluorescence normalizer.
- The test allows the quantification of the WT1 transcripts if used in combination with **REALQUALITY RQ-WT-1 STANDARD**.
- The assay shares the same thermal profile of the **REALQUALITY RS-AML1-ETO** and **RS-INV 16** kits.
- Validated on the most common Real-Time PCR thermocyclers.

KIT CONTENT:

- Ready-to-use reagents for Real-Time PCR amplification.
- Positive control WT 1 (DNA containing parts WT 1 sequences).
- Positive control ABL (DNA containing parts ABL sequences).

REALQUALITY
▸ RQ-WT-1 STANDARD
(ref. RQ-58)

CE IVD

DESCRIPTION:

Ready-to-use quantification standards for quantification of expression WT 1 and ABL gene transcripts.

The product has been validated for use with the kit REALQUALITY RS-WT-1.

KIT CONTENT:

- Quantification standards: DNA containing cDNA fragments derived from WT 1 and ABL transcripts.
- 5 standard points with concentrations ranging from 10^2 to 10^5 copies/reaction.
- The provided volume is sufficient for 10 standard curves.

ORDERING INFORMATION

BCR-ABL p210 (Real Time PCR One-Step)

CODE	PRODUCT	FORMAT
RQ-105-4M	REALQUALITY RQ-BCR-ABL p210 One-Step	50 test
RQ-105-6M	REALQUALITY RQ-BCR-ABL p210 One-Step	100 test
RQ-54-SM	REALQUALITY RQ-BCR-ABL p210 STANDARD	6 sessions
RQ-185-SM	p210 RNA REFERENCE	5 x 20 µL

BCR-ABL p190 (Real Time PCR One-Step)

CODE	PRODUCT	FORMAT
RQ-115-4M	REALQUALITY RQ-BCR-ABL p190 One-Step	50 test
RQ-115-6M	REALQUALITY RQ-BCR-ABL p190 One-Step	100 test
RQ-116-SM	REALQUALITY RQ-BCR-ABL p190 STANDARD	6 sessions

PML-RARa bcr1 (Real Time PCR One-Step)

CODE	PRODUCT	FORMAT
RQ-179-4M	REALQUALITY RQ-PML-RARa bcr1 One-Step	50 test
RQ-179-6M	REALQUALITY RQ-PML-RARa bcr1 One-Step	100 test
RQ-180-SM	REALQUALITY RQ-PML-RARa bcr1 STANDARD	6 sessions

PML-RARa bcr2 (Real Time PCR One-Step)

CODE	PRODUCT	FORMAT
RQ-181-4M	REALQUALITY RQ-PML-RARa bcr2 One-Step	50 test
RQ-181-6M	REALQUALITY RQ-PML-RARa bcr2 One-Step	100 test
RQ-182-SM	REALQUALITY RQ-PML-RARa bcr2 STANDARD	6 sessions

PML-RARa bcr3 (Real Time PCR One-Step)

CODE	PRODUCT	FORMAT
RQ-183-4M	REALQUALITY RQ-PML-RARa bcr3 One-Step	50 test
RQ-183-6M	REALQUALITY RQ-PML-RARa bcr3 One-Step	100 test
RQ-184-SM	REALQUALITY RQ-PML-RARa bcr3 STANDARD	6 sessions

ORDERING INFORMATION

INV 16 (Real Time PCR Two-Steps)

CODE	PRODUCT	FORMAT
RQ-S61-48	REALQUALITY RS-INV 16	48 test
RQ-S61-96	REALQUALITY RS-INV 16	96 test
RQ-62-ST	REALQUALITY RS-INV 16 STANDARD	10 sessions

AML1-ETO (Real Time PCR Two-Steps)

CODE	PRODUCT	FORMAT
RQ-S59-48	REALQUALITY RS-AML1-ETO	48 test
RQ-S59-96	REALQUALITY RS-AML1-ETO	96 test
RQ-60-ST	REALQUALITY RS-AML1-ETO STANDARD	10 sessions

WT 1 (Real Time PCR Two-Steps)

CODE	PRODUCT	FORMAT
RQ-S57-48	REALQUALITY RS-WT-1	48 test
RQ-S57-96	REALQUALITY RS-WT-1	96 test
RQ-58-ST	REALQUALITY RS-WT-1 STANDARD	10 sessions

Reverse Transcription Kit

CODE	PRODUCT	FORMAT
06-R1-25	Rev-T Kit RQ variant	25 test
06-R1-50	Rev-T Kit RQ variant	50 test

AB-BRO_RQ-ONCOHEMATOLOGY_e20240916

AB ANALITICA ADVANCED BIOMEDICINE

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