AmitisGen®
TECH Dev Group

# Real-Time PCR Kits


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## AML1-ETO RQ Kit

Detection and Quantitation of AML1-ETO Transcripts

AML1-ETO is the most common chromosomal aberration in de novo acute myeloid leukemia (AML) patients. This abnormality is resulted from t(8;21) (q22;q22) translocation. The translocation produces a fusion protein which inhibits myeloid transcriptional factors and as a result, cellular differentiation is blocked. This alteration occurs in approximately 7% of adult and 12% of pediatric with AML.

AML1-ETO RQ Kit provides a ready-to-use Real-Time PCR assay for detection and quantitation of AML1-ETO transcripts as well as calculation of AML1-ETO percentage.

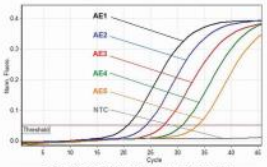

### Advantages of AML1-ETO RQ Kit

**Ready to Use**

The AML1-ETO and ABL Mixes contain all necessary reagents for Real-Time PCR and are ready to use; no further reagent or mixing is required. Reactions are prepared simply by addition of the mix directly to the tubes followed by the sample cDNA. Results can be viewed in Green/FAM channel for AML1-ETO and Yellow/VIC channel for ABL.

**Control Gene**

Kit also provides PCR Mix and Standards for assessment of ABL expression as the control gene. This would evaluate quality of the patient sample, RNA extraction and cDNA synthesis, preventing related false negative results.




Typical AML1-ETO graph in Green channel for Rotor-Gene

### Kit contents

| | | |
|---|---|---|
| AML1-ETO Mix | Ready to use PCR Master Mix containing all required reagents for detection of AML1-ETO transcripts | 480µl |
| ABL Mix | Ready to use PCR Master Mix containing all required reagents for detection of ABL transcripts | 480µl |
| AML1-ETO Standards | 5 quantitation Standards (100,000 to 10 copies /µl) | 150µl |
| ABL Standards | 4 quantitation Standards (100,000 to 100 copies /µl) | 150µl |
| Water | PCR grade Water | 200µl |
| CD & Manual | Containing all required information and instruction for use | 1 |
| Quick Guide | A short version of instruction for use | 1 |

### Kit Specifications

| | |
|---|---|
| Analytical Sensitivity | 2 copies/µl or 0.02% for AML1-ETO in context of 10,000 copies/µl of ABL transcripts |
| Reaction Type | Quantitative Real-Time PCR |
| Detection Method | TaqMan probe, Singleplex (FAM, VIC) |

### Packaging

Kit is available as 24, 48 and 96 reactions of 25µl.

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## BCR-ABL (p190) RQ Kit

Detection and Quantitation of BCR-ABL p190 Transcripts

Philadelphia chromosome is an abnormality resulted from 9;22 translocation. Consequently, ABL proto-oncogene on chromosome 9 is fused with BCR gene on chromosome 22. This fusion produces BCR-ABL protein, mostly 210kDa (b2a2 or b3a2) or 190kDa (e1a2), with constitutively active tyrosine kinase activity promoting cell proliferation and inhibition of apoptosis. The fusion gene transcript is detectable in about 95% of CML patients and some cases of ALL. Also, serial monitoring of patients for identifying and measuring BCR-ABL transcripts provides more precise assessment of response to specific therapies and prediction of those in higher risk of disease progression.

BCR-ABL (p190) RQ Kit provides a ready-to-use Real-Time PCR assay for detection and quantitation of BCR-ABL transcripts (p190, e1a2 break point only) as well as calculation of BCR-ABL%.

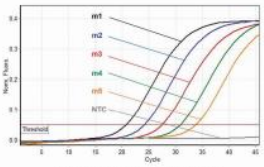

### Advantages of mbcr RQ Kit

**Ready to Use**

The mbcr and ABL Mixes contain all necessary reagents for Real-Time PCR and are ready to use; no further reagent or mixing is required. Reactions are prepared simply by addition of the mix directly to the tubes followed by the sample cDNA. Results can be viewed in Green/FAM channel for BCR-ABL and Yellow/VIC channel for ABL.

**Control Gene**

Kit also provides PCR Mix and Standards for assessment of ABL expression as the control gene. This would evaluate quality of the patient sample, RNA extraction and cDNA synthesis, preventing related false negative results.




Typical mbcr graph in Green channel for RotorGene

### Kit contents

| | | |
|---|---|---|
| mbcr RQ Mix | Ready to use PCR Master Mix containing all required reagents for detection of BCR-ABL p190 transcripts (e1a2 break points only) | 480µl |
| ABL Mix | Ready to use PCR Master Mix containing all required reagents for detection of ABL transcripts | 480µl |
| mbcr Standards | 5 quantitation Standards (100,000 to 10 copies/µl) | 150µl |
| ABL Standards | 4 quantitation Standards (100,000 to 100 copies/µl) | 150µl |
| Water | PCR grade Water | 200µl |
| CD & Manual | Containing all required information and instruction for use | 1 |
| Quick Guide | A short version of instruction for use | 1 |

### Kit Specifications

| | |
|---|---|
| Analytical Sensitivity | 10 copies/µl or 0.2% in the context of 5,000 copies/µl of ABL transcripts |
| Reaction Type | Quantitative Real-Time PCR |
| Detection Method | TaqMan probe, Singelplex (FAM, VIC) |

### Packaging

Kit is available as 24, 48 and 96 reactions of 25µl.

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## BCR-ABL (p210) RQ Kit

Detection and Quantitation of BCR-ABL p210 Transcripts

BCR-ABL also known as Philadelphia chromosome is an abnormality resulted from 9;22 translocation. Consequently, ABL proto-oncogene on chromosome 9 is fused with BCR gene on chromosome 22 (b2a2 or b3a2). This fusion produces mostly 210 or 190 kDa BCR-ABL protein with constitutively active tyrosine kinase activity promoting cell proliferation and inhibition of apoptosis. The fusion gene transcript is detectable in about 95% of CML patients and some cases of ALL. Also, serial monitoring of patients for identifying and measuring BCR-ABL transcripts provides more precise assessment of response to specific therapies and prediction of those in higher risk of disease progression.

BCR-ABL (p210) RQ Kit provides a ready-to-use Real-Time PCR assay for detection and quantitation of BCR-ABL transcripts (p210, b2a2 or b3a2 break points only) as well as calculation of BCR-ABL%.

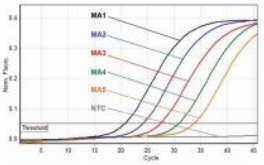

### Advantages of MBCR RQ Kit

**Ready to Use**

The MBCR and ABL Mixes contain all necessary reagents for Real-Time PCR and are ready to use; no further reagent or mixing is required. Reactions are prepared simply by addition of the mix directly to the tubes followed by the sample cDNA. Results can be viewed in Green/FAM channel for BCR-ABL and Yellow/VIC channel for ABL.

**Control Gene**

Kit also provides PCR Mix and Standards for assessment of ABL expression as the control gene. This would evaluate quality of the patient sample, RNA extraction and cDNA synthesis, preventing related false negative results.




Typical MBCR graph in Green channel for RotorGene

### Kit contents

| | | |
|---|---|---|
| MBCR RQ Mix | Ready to use PCR Master Mix containing all required reagents for detection of BCR-ABL p210 transcripts ( b2a2 or b3a2 break points only) | 480µl |
| ABL Mix | Ready to use PCR Master Mix containing all required reagents for detection of ABL transcripts | 480µl |
| MBCR Standards | 5 quantitation Standards (100,000 to 10 copies/µl) for MBCR and ABL | 250µl |
| Water | PCR grade Water | 200µl |
| CD & Manual | Containing all required information and instruction for use | 1 |
| Quick Guide | A short version of instruction for use | 1 |

### Kit Specifications

| | |
|---|---|
| Analytical Sensitivity | 4 copies/µl or 0.08% for BCR-ABL in the context of 5,000 copies/µl of ABL transcripts |
| Reaction Type | Quantitative Real-Time PCR |
| Detection Method | TaqMan probe, Singelplex (FAM, VIC) |

### Packaging

Kit is available as 24, 48 and 96 reactions of 25µl.

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BRAF RQ Kit

# BRAF RQ Kit

## Detection of BRAF Mutations

BRAF oncogene is among the most frequently mutated kinases in human cancer. Mutations in codon V600 have been reported in different types of cancers including 40%-50% of melanomas, 10%-70% of thyroid carcinomas, 10% of colorectal cancers and 3%-5% of Non-Small Cell Lung Cancers (NSCLC). Most of the BRAF mutations are located in codon 600 and constitute V600E, V600Ec, V600D, V600K, V600R.

BRAF RQ Kit provides a ready-to-use Real-Time PCR assay for detection of these 5 mutations.


### Advantages of BRAF RQ Kit

**Ready to Use**

The BRAF Mixes contain all necessary reagents for Real-Time PCR and are ready to use; no further reagent or mixing is required. Reactions are prepared simply by addition of the mix directly to the tubes followed by the sample DNA. Results can be viewed in Green/FAM and Yellow/VIC channels.

### Kit contents

| | | |
|---|---|---|
| BRAF Control Mix | PCR Master Mix for quality control | 2×480µl |
| V600E Mix | PCR Master Mix for V600E mutation | 480µl |
| V600Ec Mix | PCR Master Mix for V600Ec mutation | 480µl |
| V600D Mix | PCR Master Mix for V600D mutation | 480µl |
| V600K Mix | PCR Master Mix for V600K mutation | 480µl |
| V600R Mix | PCR Master Mix for V600R mutation | 480µl |
| BRAF Positive Control | Positive Control | 250µl |
| BRAF Negative Control | Negative Control | 250µl |
| Water | PCR grade Water | 200µl |
| CD & Manual | Containing all required information and instruction for use | 1 |
| Quick Guide | A short version of instruction for use | 1 |

### Kit Specifications

| | |
|---|---|
| Analytical Sensitivity | 0.5%-2%, Depending on the mutation type |
| Reaction Type | Qualitative Real-Time PCR |
| Detection Method | TaqMan probe, Singleplex/ Duplex (FAM, VIC) |

### Packaging

Kit is available as 24 and 48 reactions of 25µl.

EGFR RQ Kit

# EGFR RQ Kit

## Detection of EGFR Mutations

Epidermal Growth Factor Receptor (EGFR), is a tyrosine kinase receptor and is considered as an oncogene. EGFR is involved in regulation of cellular proliferation, differentiation and survival. Mutations in EGFR exons 18, 19, 20 and 21 are associated with the development of different human cancers specially Non-Small Cell Lung Cancer (NSCLC) and glioblastoma. Since, the choice of anti-EGFR therapies are highly dependent on the EGFR mutations, it is essential that patients are tested for these mutations.

This kit provides ready to use reagents for detection of 34 mutations. Detected mutations include three point mutations in exon 18 (G719A, G719S and G719C without differentiating them), 24 deletions in exon 19 (without differentiation between them), three insertion (without differentiation between them) and two point mutations in exon 20 (S768I, T790M) and two point mutations in exon 21 (L858R, L861Q).

EGFR RQ Kit provides a ready-to-use Real-Time PCR assay for detection of these 34 mutations.


### Advantages of EGFR RQ Kit

**Ready to Use**

The EGFR Mixes contain all necessary reagents for Real-Time PCR and are ready to use; no further reagent or mixing is required. Reactions are prepared simply by addition of the mix directly to the tubes followed by the sample DNA. Results can be viewed in Green/FAM and Yellow/VIC channels.

### Kit contents

| | | |
|---|---|---|
| EGFR Control Mix | PCR Master Mix for quality control | 2×480µl |
| G719X Mix | PCR Master Mix for G719A/G719S/G719C mutations | 480µl |
| 19Del Mix | PCR Master Mix for exon 19 Deletions | 480µl |
| 20Ins Mix | PCR Master Mix for exon 20 insertions | 480µl |
| S768I Mix | PCR Master Mix for S768I mutation | 480µl |
| T790M Mix | PCR Master Mix for T790M mutation | 480µl |
| L858R Mix | PCR Master Mix for L858R mutation | 480µl |
| L861Q Mix | PCR Master Mix for L861Q mutation | 480µl |
| EGFR Positive Control | Positive Control | 250µl |
| EGFR Negative Control | Negative Control | 250µl |
| Water | PCR grade Water | 200µl |
| CD & Manual | Containing all required information and instruction for use | 1 |
| Quick Guide | A short version of instruction for use | 1 |

### Kit Specifications

| | |
|---|---|
| Analytical Sensitivity | 1%-8%, Depending on the mutation type |
| Reaction Type | Qualitative Real-Time PCR |
| Detection Method | TaqMan probe, Singleplex/Duplex (FAM, VIC) |

### Packaging

Kit is available as 24 and 48 reactions of 25µl.

ETV6-RUNX1 RQ Kit

# ETV6-RUNX1 RQ Kit

## Detection and Quantitation of ETV6-RUNX1 (TEL-AML1) Transcripts

ETV6-RUNX1 (TEL-AML1) is an abnormality resulted from 21;12 translocation. RUNX1 gene, encodes a protein involved in transcriptional control of hematopoiesis. However, as a result of this translocation, it is repressed by ETV6-RUNX1 fusion protein.

This alteration occurs in approximately 25% of childhood ALL diagnosed between the ages of 2-10 years.

ETV6-RUNX1 (TEL-AML1) RQ Kit provides a ready-to-use Real-Time PCR assay for detection and quantitation of ETV6-RUNX1 transcripts as well as calculation of ETV6-RUNX1 percentage.


### Advantages of ETV6-RUNX1 RQ Kit

**Ready to Use**

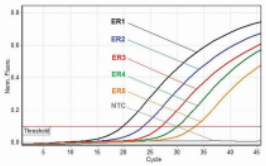
The ETV6-RUNX1 and ABL Mixes contain all necessary reagents for Real-Time PCR and are ready to use; no further reagent or mixing is required. Reactions are prepared simply by addition of the mix directly to the tubes followed by the sample cDNA. Results can be viewed in Green/FAM channel for ETV6-RUNX1 and Yellow/VIC channel for ABL.

**Control Gene**

Kit also provides PCR Mix and Standards for assessment of ABL expression as the control gene. This would evaluate quality of the patient sample, RNA extraction and cDNA synthesis, preventing related false negative results.

### Kit contents

| | | |
|---|---|---|
| ETV6-RUNX1 Mix | Ready to use PCR Master Mix containing all required reagents for detection of ETV6-RUNX1 transcripts | 480µl |
| ABL Mix | Ready to use PCR Master Mix containing all required reagents for detection of ABL transcripts | 480µl |
| ETV6-RUNX1 Standards | 5 quantitation Standards (100,000 to 10 copies/µl) | 150µl |
| ABL Standards | 4 quantitation Standards (100,000 to 100 copies/µl) | 150µl |
| Water | PCR grade Water | 200µl |
| CD & Manual | Containing all required information and instruction for use | 1 |
| Quick Guide | A short version of instruction for use | 1 |




Typical ETV6-RUNX1 graph in Green channel for Rotor-Gene

### Kit Specifications

| | |
|---|---|
| Analytical Sensitivity | 2 copies/µl or 0.02% for TEL-AML1 in context of 10,000 copies/µl of ABL transcripts |
| Reaction Type | Quantitative Real-Time PCR |
| Detection Method | TaqMan probe, Singleplex (FAM, VIC) |

### Packaging

Kit is available as 24, 48 and 96 reactions of 25µl.

JAK2 MQ Kit

# JAK2 MQ Kit

## Detection and Quantitation of JAK2 V617F Mutation

JAK2 (Janus Kinase 2) is a Tyrosine Kinase located in cytoplasm with essential role in signaling pathways for cytokines and growth factors. The acquired mutation G1849T replaces valine with phenylalanine (V617F). This substitution results in constitutively active JAK2 which leads to uncontrolled cell proliferation in the absence of growth factors. This mutation is found in the majority of BCR-ABL-negative myeloproliferative disorders (MPDs) and has become a main diagnostic test for polycythemia vera (PV), essential thrombocythemia (ET) and primary myelofibrosis (PMF).

JAK2 MQ Kit provides a ready-to-use Real-Time PCR assay for detection and quantitation of JAK2 V617F mutation.

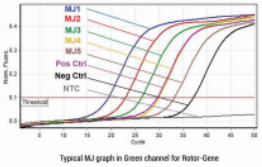

### Advantages of JAK2 MQ Kit

**Ready to Use**

The MJ and WJ Mixes contain all necessary reagents for Real-Time PCR and are ready to use; no further reagent or mixing is required. Reactions are prepared simply by addition of the mix directly to the tubes followed by the sample DNA. Results can be viewed in Green/FAM channel for MJ and WJ.

### Kit contents

| | | |
|---|---|---|
| MJ Mix | Ready to use PCR Master Mix containing all required reagents for detection of JAK2 (V617F) mutation | 480µl |
| WJ Mix | Ready to use PCR Master Mix containing all required reagents for detection of Wild type alleles | 480µl |
| MJ Standards | 5 quantitation Standards (100,000 to 10 copies/µl) | 150µl |
| WJ Standards | 5 quantitation Standards (100,000 to 10 copies/µl) | 150µl |
| Positive Control 2.5% | Positive Control 2.5% | 50µl |
| Negative Control | Negative Control | 50µl |
| Water | PCR grade Water | 200µl |
| CD & Manual | Containing all required information and instruction for use | 1 |
| Quick Guide | A short version of instruction for use | 1 |




Typical MJ graph in Green channel for Rotor-Gene

### Kit Specifications

| | |
|---|---|
| Analytical Sensitivity | 0.1% in context of 5000 copies/µl wild type alleles |
| Reaction Type | Quantitative Real-Time PCR |
| Detection Method | TaqMan probe, Singleplex (FAM) |

### Packaging

Kit is available as 24, 48 and 96 reactions of 25µl.

# JAK2 RQ Kit

## Detection of JAK2 Mutation (V617F)

JAK2 (Janus Kinase 2) is a Tyrosine Kinase located in cytoplasm with essential role in signaling pathways for cytokines and growth factors. The acquired mutation G1849T replaces valine with phenylalanine (V617F). This substitution results in constitutively active JAK2 which leads to uncontrolled cell proliferation in the absence of growth factors. This mutation is found in the majority of BCR-ABL-negative myeloproliferative disorders (MPDs) and has become a main diagnostic test for polycythemia vera (PV), essential thrombocythemia (ET) and primary myelofibrosis (PMF).

JAK2 RQ Kit provides a ready-to-use Real-Time PCR assay for detection of JAK2 V617F mutation.

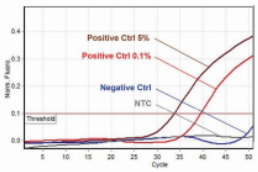

### Advantages of JAK2 RQ Kit

**Ready to Use**

The JAK2 Mix contains all necessary reagents for Real-Time PCR and is ready to use; no further reagent or mixing is required. Reactions are prepared simply by addition of the mix directly to the tubes followed by the sample DNA. Results can be viewed in Green/FAM channel.

**Internal Control**

The PCR Mix detects also a housekeeping gene in Yellow/VIC channel. Internal Control ensures quality of patient sample and DNA extraction and also prevents false negative results by PCR inhibition or setup errors.




Typical graph of JAK2 Controls in Green channel for Rotor-Gene

### Kit contents

| | | |
|---|---|---|
| JAK2 RQ Mix | Ready to use PCR Master Mix containing all required reagents for JAK2 V617F mutation | 480µl |
| Positive Control 5% | Positive Control 5% | 50µl |
| Positive Control 0.1% | Positive Control 0.1% | 50µl |
| Negative Control | Negative Control | 50µl |
| Water | PCR grade Water | 200µl |
| CD & Manual | Containing all required information and instruction for use | 1 |
| Quick Guide | A short version of instruction for use | 1 |

### Kit Specifications

| | |
|---|---|
| Analytical Sensitivity | 0.1% in 10-50 ng/µl DNA |
| Reaction Type | Qualitative Real-Time PCR |
| Detection Method | TaqMan probe, Duplex (FAM, VIC) |

### Packaging

Kit is available as 24, 48 and 96 reactions of 25µl.



# KRAS RQ Kit

## Detection of KRAS Mutations

Colorectal cancer (CRC) is among the most prevalent cancers worldwide. Treatment with monoclonal antibodies against Epidermal Growth Factor Receptor (Anti-EGFR) has shown to be effective for CRC patients. However, Anti-EGFR would be ineffective in presence of some KRAS mutations including mutations in codons 12 and 13. This is the same for treating Non-Small Cell Lung Cancer (NSCLC) with Anti-EGFR. Therefore, determining the KRAS mutation status is essential for these patients. It should be noted that, 95% and 88% of KRAS mutations in CRC and NSCLC patients respectively are reported in codons 12 and 13 including G12A, G12C, G12D, G12R, G12S, G12V and G13D.

KRAS RQ Kit provides a ready-to-use Real-Time PCR assay for detection of these 7 mutations.


### Advantages of KRAS RQ Kit

**Ready to Use**

The KRAS Mixes contain all necessary reagents for Real-Time PCR and are ready to use; no further reagent or mixing is required. Reactions are prepared simply by addition of the mix directly to the tubes followed by the sample DNA. Results can be viewed in Green/FAM and Yellow/VIC channels.

### Kit contents

| | | |
|---|---|---|
| Control Mix | PCR Master Mix for quality control | 2×480µl |
| G12A Mix | PCR Master Mix to check G12A mutation | 480µl |
| G12C Mix | PCR Master Mix to check G12C mutation | 480µl |
| G12D Mix | PCR Master Mix to check G12D mutation | 480µl |
| G12R Mix | PCR Master Mix to check G12R mutation | 480µl |
| G12S Mix | PCR Master Mix to check G12S mutation | 480µl |
| G12V Mix | PCR Master Mix to check G12V mutation | 480µl |
| G13D Mix | PCR Master Mix to check G13D mutation | 480µl |
| KRAS Positive Control | Positive Control | 250µl |
| KRAS Negative Control | Negative Control | 250µl |
| Water | PCR grade Water | 200µl |
| CD & Manual | Containing all required information and instruction for use | 1 |
| Quick Guide | A short version of instruction for use | 1 |

### Kit Specifications

| | |
|---|---|
| Analytical Sensitivity | 1%-4%, Depending on the mutation |
| Reaction Type | Qualitative Real-Time PCR |
| Detection Method | TaqMan probe, Singleplex/Duplex (FAM, VIC) |

### Packaging

Kit is available as 24 and 48 reactions of 25µl.



# PML-RARA (bcr1) RQ Kit

## Detection and Quantitation of PML-RARA (bcr1) Transcripts

PML-RARA is an abnormality resulted from t(15;17) (q22; q21) translocation. This translocation results in fusion of PML (promyelocytic) gene with RARA (retinoic acid receptor alpha) gene, and production of chimeric PML-RARA protein which is a transcription repressor and impairs the myeloid differentiation. While RARA breakpoints always occur in intron 2, PML breakpoints involves three different regions of intron 6 (55%), exon 6 (5%) and intron 3 (40%). The resulted isoforms of PML-RARA are respectively called bcr1/Long/L, bcr2/Variant/V and bcr3/Short/S.

PML-RARA accounts for more than 90% of APL (acute progranulocytic leukemia) cases, 10%-15% of AML (acute myeloid leukemia) cases.

PML-RARA (bcr1) RQ Kit provides a ready-to-use Real-Time PCR assay for detection and quantitation of PML-RARA (bcr1) transcripts and monitoring MRD.

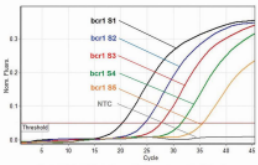

### Advantages of PML-RARA (bcr1) RQ Kit

**Ready to Use**

The bcr1 and ABL Mixes contain all necessary reagents for Real-Time PCR and are ready to use; no further reagent or mixing is required. Reactions are prepared simply by addition of the mix directly to the tubes followed by the sample cDNA. Results can be viewed in Green/FAM channel for bcr1 and Yellow/VIC channel for ABL.

**Control Gene**

Kit also provides PCR Mix and Standards for assessment of ABL expression as the control gene. This would evaluate quality of the patient sample, RNA extraction and cDNA synthesis, preventing related false negative results.




Typical PML-RARA, bcr1 graph in Green channel for Rotor-Gene

### Kit contents

| | | |
|---|---|---|
| bcr1 RQ Mix | Ready to use PCR Master Mix containing all required reagents for detection of bcr1 transcripts | 480µl |
| ABL Mix | Ready to use PCR Master Mix containing all required reagents for detection of ABL transcripts | 480µl |
| bcr1 Standards | 5 quantitation Standards (100,000 to 10 copies/µl) | 150µl |
| ABL Standards | 4 quantitation Standards (100,000 to 100 copies/µl) | 150µl |
| Water | PCR grade Water | 200µl |
| CD & Manual | Containing all required information and instruction for use | 1 |
| Quick Guide | A short version of instruction for use | 1 |

### Kit Specifications

| | |
|---|---|
| Analytical Sensitivity | 2 copies/µl or 0.02% for bcr1 in the context of 10,000 copies/µl of ABL transcripts |
| Reaction Type | Quantitative Real-Time PCR |
| Detection Method | TaqMan probe, Singleplex (FAM, VIC) |

### Packaging

Kit is available as 24, 48 and 96 reactions of 25µl.



# PML-RARA (bcr2) RQ Kit

## Detection and Quantitation of PML-RARA (bcr2) Transcripts

PML-RARA is an abnormality resulted from t(15;17) (q22; q21) translocation. This translocation results in fusion of PML (promyelocytic) gene with RARA (retinoic acid receptor alpha) gene, and production of chimeric PML-RARA protein which is a transcription repressor and impairs the myeloid differentiation. While RARA breakpoints always occur in intron 2, PML breakpoints involves three different regions of intron 6 (55%), exon 6 (5%) and intron 3 (40%). The resulted isoforms of PML-RARA are respectively called bcr1/Long/L, bcr2/Variant/V and bcr3/Short/S.

PML-RARA accounts for more than 90% of APL (acute progranulocytic leukemia) cases, 10%-15% of AML (acute myeloid leukemia) cases.

PML-RARA (bcr2) RQ Kit provides a ready-to-use Real-Time PCR assay for detection and quantitation of PML-RARA (bcr2) transcripts and monitoring MRD.

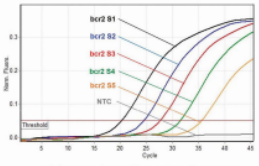

### Advantages of PML-RARA (bcr2) RQ Kit

**Ready to Use**

The bcr2 and ABL Mixes contain all necessary reagents for Real-Time PCR and are ready to use; no further reagent or mixing is required. Reactions are prepared simply by addition of the mix directly to the tubes followed by the sample cDNA. Results can be viewed in Green/FAM channel for bcr2 and Yellow/VIC channel for ABL.

**Control Gene**

Kit also provides PCR Mix and Standards for assessment of ABL expression as the control gene. This would evaluate quality of the patient sample, RNA extraction and cDNA synthesis, preventing related false negative results.




Typical PML-RARA, bcr2 graph in Green channel for Rotor-Gene

### Kit contents

| | | |
|---|---|---|
| bcr2 RQ Mix | Ready to use PCR Master Mix containing all required reagents for detection of bcr2 transcripts | 480µl |
| ABL Mix | Ready to use PCR Master Mix containing all required reagents for detection of ABL transcripts | 480µl |
| bcr2 Standards | 5 quantitation Standards (100,000 to 10 copies/µl) | 150µl |
| ABL Standards | 4 quantitation Standards (100,000 to 100 copies/µl) | 150µl |
| Water | PCR grade Water | 200µl |
| CD & Manual | Containing all required information and instruction for use | 1 |
| Quick Guide | A short version of instruction for use | 1 |

### Kit Specifications

| | |
|---|---|
| Analytical Sensitivity | 2 copies/µl or 0.02% for bcr2 in the context of 10,000 copies/µl of ABL transcripts |
| Reaction Type | Quantitative Real-Time PCR |
| Detection Method | TaqMan probe, Singleplex (FAM, VIC) |

### Packaging

Kit is available as 24, 48 and 96 reactions of 25µl.

# PML-RARA (bcr3) RQ Kit

## Detection and Quantitation of PML-RARA (bcr3) Transcripts

PML-RARA is an abnormality resulted from t(15;17) (q22; q21) translocation. This translocation results in fusion of PML (promyelocytic) gene with RARA (retinoic acid receptor alpha) gene, and production of chimeric PML-RARA protein which is a transcription repressor and impairs the myeloid differentiation. While RARA breakpoints always occur in intron 2, PML breakpoints involves three different regions of intron 6 (55%), exon 6 (5%) and intron 3 (40%). The resulted isoforms of PML-RARA are respectively called bcr1/Long/L, bcr2/Variant/V and bcr3/Short/S.

PML-RARA accounts for more than 90% of APL (acute progranulocytic leukemia) cases, 10%-15% of AML (acute myeloid leukemia) cases.

PML-RARA (bcr3) RQ Kit provides a ready-to-use Real-Time PCR assay for detection and quantitation of PML-RARA (bcr3) transcripts and monitoring MRD.

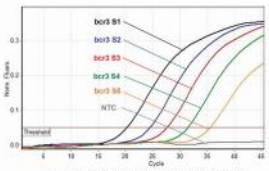

### Advantages of PML-RARA (bcr3) RQ Kit

**Ready to Use**

The bcr3 and ABL Mixes contain all necessary reagents for Real-Time PCR and are ready to use; no further reagent or mixing is required. Reactions are prepared simply by addition of the mix directly to the tubes followed by the sample cDNA. Results can be viewed in Green/FAM channel for bcr3 and Yellow/VIC channel for ABL.

**Control Gene**

Kit also provides PCR Mix and Standards for assessment of ABL expression as the control gene. This would evaluate quality of the patient sample, RNA extraction and cDNA synthesis, preventing related false negative results.




Typical PML-RARA, bcr3 graph in Green channel for Rotor-Gene

### Kit contents

| | | |
|---|---|---|
| bcr3 RQ Mix | Ready to use PCR Master Mix containing all required reagents for detection of bcr3 transcripts | 480µl |
| ABL Mix | Ready to use PCR Master Mix containing all required reagents for detection of ABL transcripts | 480µl |
| bcr3 Standards | 5 quantitation Standards (100,000 to 10 copies/µl) | 150µl |
| ABL Standards | 4 quantitation Standards (100,000 to 100 copies/µl) | 150µl |
| Water | PCR grade Water | 200µl |
| CD & Manual | Containing all required information and instruction for use | 1 |
| Quick Guide | A short version of instruction for use | 1 |

### Kit Specifications

| | |
|---|---|
| Analytical Sensitivity | 2 copies/µl or 0.02% for bcr3 in the context of 10,000 copies/µl of ABL transcripts |
| Reaction Type | Quantitative Real-Time PCR |
| Detection Method | TaqMan probe, Singleplex (FAM, VIC) |

### Packaging

Kit is available as 24, 48 and 96 reactions of 25µl.

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