

## Additional Information

**For use with:** AMD (QPCR) Kit. QPCR Kit is a real-time PCR kit with a wide range of applications for researchers from gene expression analysis, cDNA, population genotyping studies, to the multiplex detection of several disease targets real-time PCR with excellent sensitivity and specificity. Please familiarise yourself with the QPCR instrument before using the AMD BCR/ABL PCR Kit "CE-IVD".

## Additional Equipment Required (not provided)

**RNA Extraction:** AMD Manufacture a RNA extraction kit that can be used to extract the RNA from blood samples.

**PCR Instrument:** AMD Manufacture a high standard QPCR Real Time PCR system that is recommended for use with this PCR kit.

**Disposables:** AMD manufacture high quality PCR plastic wear suitable for use with this kit. It is also recommended that correct PPE including gloves is used throughout.

**Other Laboratory Equipment:** Vortex, micro centrifuge, Micro pipettes and tips.

**Sample storage:** As a general rule, multiple freeze-thaws should be avoided. The most practical way to address this concern is by aliquoting samples after collection.

**Sample transport:** Sample material should be transported in a shatterproof transport container as a matter of principle. Thus, a potential danger of infection due to a leakage of sample can be avoided. The samples should be transported following the local and national instructions for the transport of pathogen material. The samples should be shipped within 6 hours. It is not recommended to store the samples where they have been collected. It is possible to ship the samples by mail, following the legal instructions for the transport of pathogen material. We recommend the sample transport with a courier.

**Warnings and precautions:** When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate safety data sheets (SDSs). Discard sample and assay waste according to your local safety regulations.

**Product Use Limitations:** All reagents may exclusively be used in in vitro diagnostics. The product is to be used by personnel specially instructed and trained in the in vitro diagnostics procedures only. Strict compliance with the user manual is required for optimal PCR results. Attention should be paid to expiration dates printed on the box and labels of all components. Do not use expired components. Although rare, mutations within the highly-conserved regions of the viral genome covered by the kit's primers and/or probe may result in under quantitation or failure to detect the presence of the virus in these cases. Validity and performance of the assay design are revised at regular intervals.

**Contact:** Any queries, comments or complaints please refer to our website at: [www.am-diagnostics.co.uk](http://www.am-diagnostics.co.uk) or email: [info@am-diagnostics.co.uk](mailto:info@am-diagnostics.co.uk)



## Advanced Molecular Diagnostics BCR/ABL QPCR Kits "CE-IVD" Package Insert

**The assay is an in vitro PCR reaction assay for the quantitation determination of BCR-ABL1 and ABL1 transcript in total RNA from Whole Blood samples based on TaqMan® detection method for BCR-ABL with high sensitive two steps QPCR kit.**

For use in In Vitro Diagnostics.

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## Kit Contents

1 x 1.4 ml BCR/ABL QPCR one step Multiplex  
Detection Master Mix  
1 x 0.5 ml BCR/ABL Internal Control  
1 x 0.1 ml BCR/ABL Positive Control  
1 x 1 ml PCR Grade Water

## Overview

BCR-ABL is a fusion gene, found in an abnormality in chromosome 22 of leukaemia cancer cells the cause of chronic myelogenous leukaemia (CML) and some other leukaemia's can be traced to a single, specific genetic abnormality in one chromosome

The BCR-ABL1 gene sequence is one such acquired change that is formed when pieces of chromosome 9 and chromosome 22 break off and switch places. When this occurs, the ABL1 region in chromosome 9 fuses with the BCR gene region in chromosome 22. This type of change is called a reciprocal translocation and is often abbreviated as t(9;22). The resulting chromosome 22 that has the BCR-ABL1 gene sequence is known as the Philadelphia (Ph) chromosome because that is where it was first discovered.

## Storage Specifications

The kits should be transported and stored at temperatures between -85 °C and -10 °C. The kit will remain stable at least until the expiry date printed on the package, if the storage temperature is kept. Repeated freezing and thawing of the kit components may result in lower detection quality.

## Basic Principles

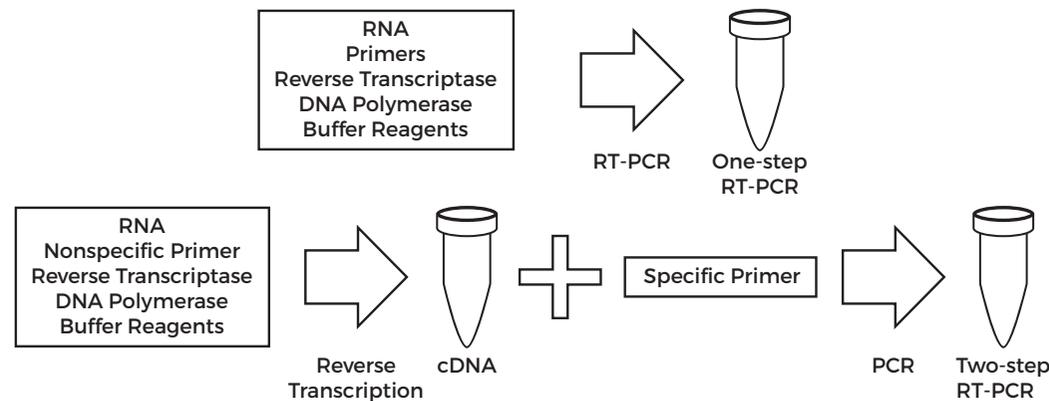
RT-QPCR (reverse transcription – quantitative PCR) has the ability to convert RNA into cDNA (complimentary DNA) through enzymes called reverse transcriptases. Reverse transcriptases can be found naturally and are used in QPCR mainly when dealing with retroviruses. Reverse transcription occurs in the cytoplasm and generates a linear DNA duplex through a series of complex steps. Qualitative study of gene expression, quantitative PCR can be utilized for quantification of RNA, in both relative and absolute terms, by incorporating qPCR into the technique.

## Protocols

**Sample Collection:** The sample for AMD BCR/ABL PCR Kit “CE-IVD” should be collected via whole blood samples, please ensure that the sample is stored correctly and kept away from any contamination.

**Sample Preparation:** For optimal results use AMD RNA Extraction Kit to elute the RNA from the sample.

## PCR Set up:



## PCR Set up Cont.

Product	Volume
MasterMix	10ul
RT-Enzyme	1ul
RNA Sample	14ul

**Thermal Profile:** Set the QPCR instrument to the stages below

Stage/Step	Temperature	Time
Stage 1: Step 1	55oC	15 min
Stage 1: Step 2	95oC	2 min
45 Cycles		
Stage 2: Step 1	95oC	10 Sec
Stage 2: Step 2	55oC	20 Sec
Stage 2: Step 3	72oC	10 Sec

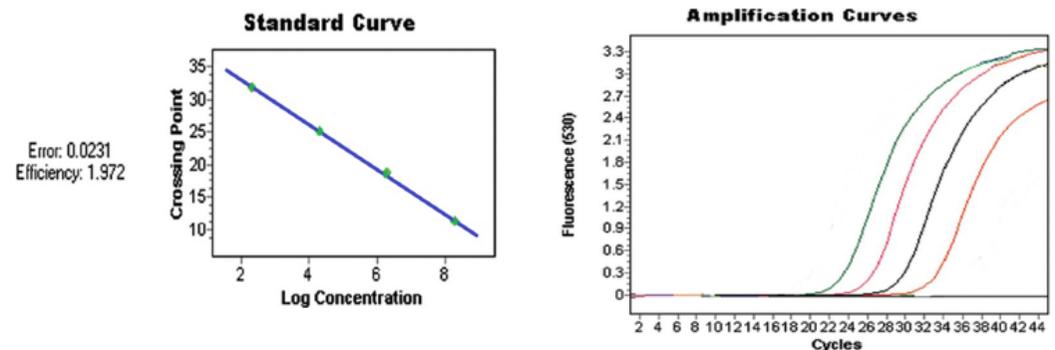
It is essential to ensure the correct protocols for every product are followed strictly

## Technical Specifications

**Quality:** Advanced Molecular Diagnostics Human BCR-ABL kit is very sensitive kit reaches up to 0,01 % BCR/ABL positive cells per “rxn volume 25ul” under our validation methods and devices.

**Sensitivity:** Advanced Molecular Diagnostics Human BCR-ABL kit is very specific up to 100% for Human BCR-ABL under our validation methods and devices.

**Data Analysis:** Similar to other real-time PCR software AMD PCR software offers several analysis modules, including quantification, melt curve, gene expression, allelic discrimination, and end-point analyses. a data file is automatically generated after a run with the gene expression module. Easily view up to six different charts or tables, such as the amplification plot, standard curve, gene expression chart, plate layout, or melt peak with the Custom Data View tab.



The software used will show screens including a CT reading and the linearity of the samples used.

**Linear Range:** Up to 10<sup>10</sup> copies