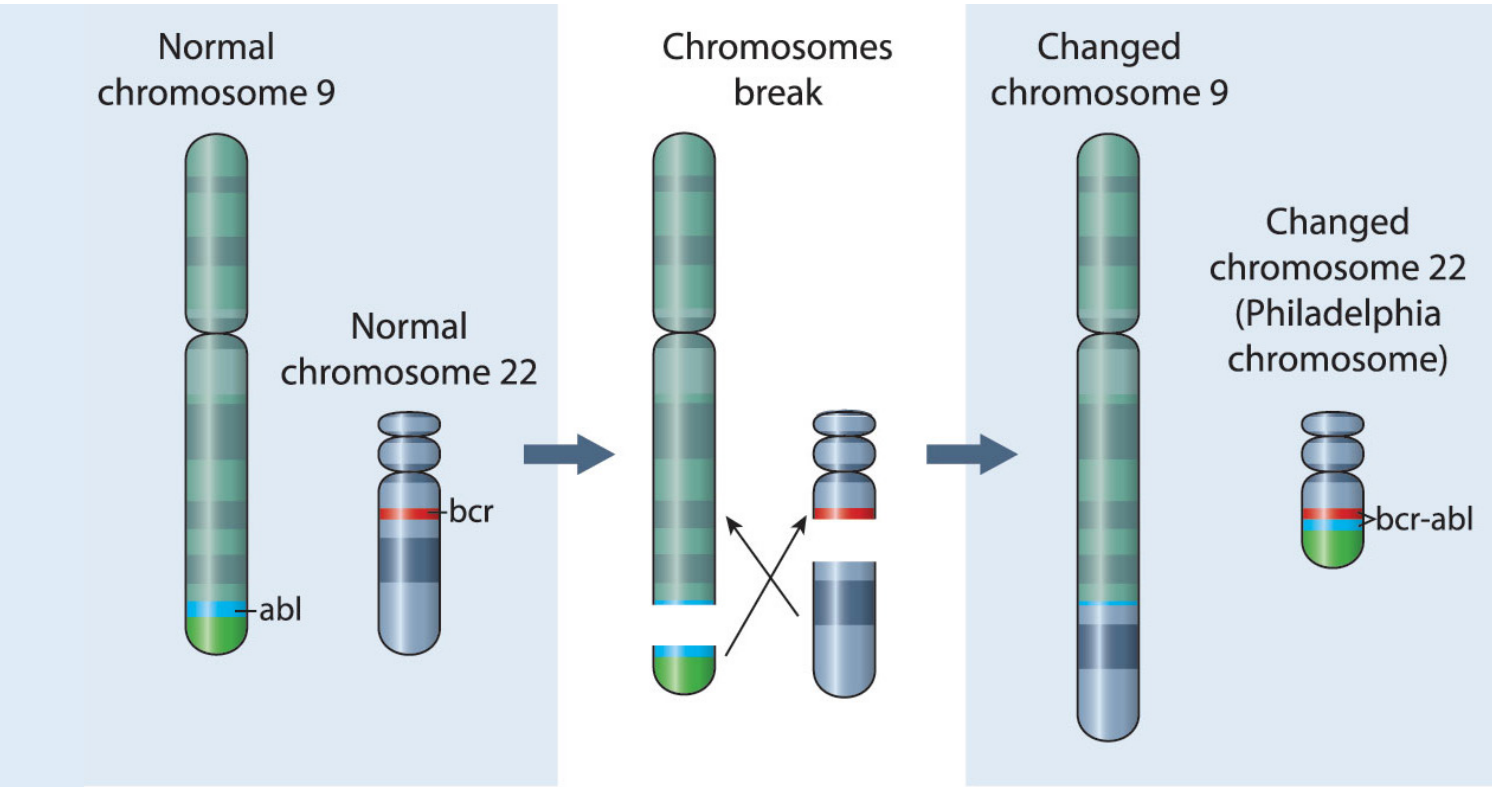
GENEPATH Dx™ *Better healthcare through next generation diagnostics*



*Gene*Path Dx *BCR-ABL* IS RQ-PCR test kit

Monitoring of Chronic Myeloid Leukemia (CML) Minimal Residual Disease (MRD) through relative quantification of the *BCR-ABL* fusion transcript

BCR-ABL, the molecular aberration present in patients with Chronic Myeloid Leukemia (CML), is a valuable tumor marker whose detection influences prognosis and clinical management decisions. The presence of *BCR-ABL* [t(9;22)] fusion transcripts confirm the diagnosis of CML. The quantitative detection of *BCR-ABL* transcripts (Minimal Residual Disease or MRD) by real-time quantitative reverse transcription polymerase chain reaction (RT-qPCR) helps in monitoring treatment response to tyrosine kinase inhibitors (e.g. Imatinib).

Salient Features:

- Minimal Residual Disease determination through *BCR-ABL/ABL* ratio reported on the International Scale (IS)*
- Single-pot duplex assay with integrated reverse transcription (RT) / cDNA synthesis and qPCR
- Wide dynamic range / high sensitivity providing accurate quantification of the Major *BCR-ABL* e13/e14-a2 (p210) and *ABL* transcripts
- Reactions incorporate the dUTP / UNG system which helps to minimise carry-over contamination
- Two channel assay with broad instrument compatibility (kit validated on the Qiagen Rotor-Gene Q, Bio-Rad CFX96, Bio-Rad Opus, Roche LightCycler II 480, Thermo/ABI QuantStudio5 and StepOne instruments; fluorophores compatible with most real time thermocyclers)
- Secure online tool to assist with data analysis

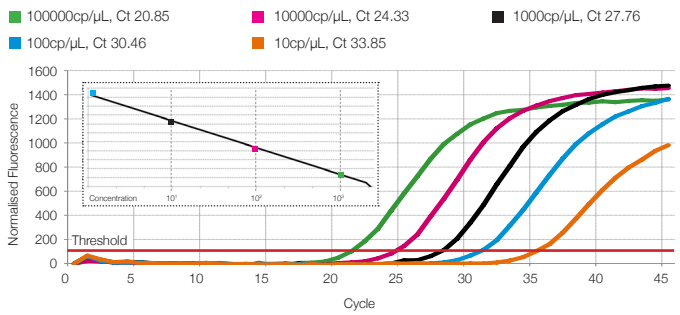
*when used in conjunction with the recommended *Gene*Path Dx RNA extraction protocol

Performance Characteristics:

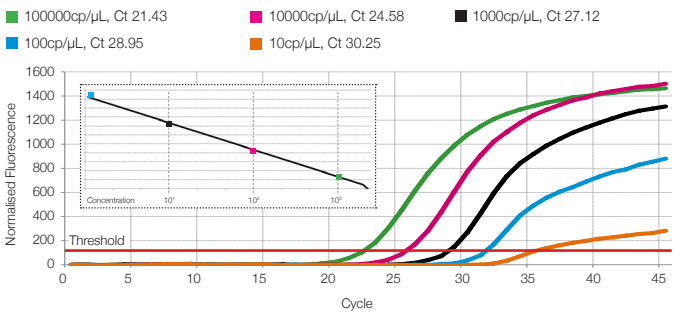
1. Analytical Sensitivity:

The *BCR-ABL* and *ABL* assays used in this test are capable of detecting down to 10 copies/µL of transcripts per PCR and a > 4.8 logarithmic reduction in relative expression between *BCR-ABL* and *ABL* (MR > 4.8).

BCR-ABL



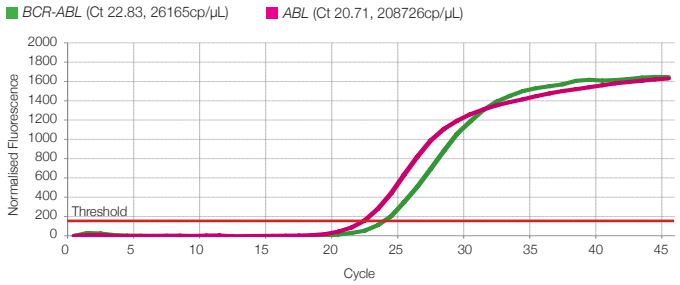
ABL



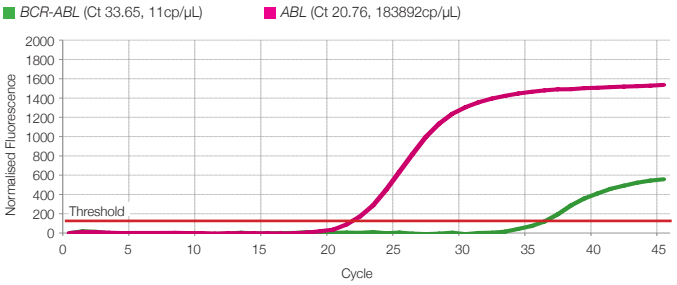
2. Correlation with WHO standard reference material:

Amplification plots of %*BCR-ABL/ABL* on WHO reference material ranging from 10% to 0.0032% (representative graphs given below):

BCR-ABL/ABL **(input standard - 10%, calculated IS value - 9%)**



BCR-ABL/ABL **(input standard - 0.0032%, calculated IS value - 0.0045%)**



Note: Reporting of *BCR-ABL* ratios on the International Scale (IS) is only supported when this kit is used in conjunction with the recommended sample preparation protocol.

International Scale (IS) and log Molecular Reduction (MR) correlation:

% *BCR-ABL/ABL* (IS)	Log Molecular Reduction (MR)
10	1
1	2
0.1	3
0.01	4
0.0032	4.5

3. Analytical Specificity:

Laboratory (wet lab)* and *in-silico* analysis (bioinformatic) show that the test and its components are highly specific to *BCR-ABL* major and demonstrate no cross-reactivity to or interference from human genomic DNA, other human transcripts or commonly encountered pathogens or commensals.

*Other fusion transcripts tested for cross-reactivity and interference include*BCR-ABL* minor (p190) (e1-a2),*BCR-ABL* micro (p230) (e19-a2, e6-a2, e8-a2, e1-a3, e6-a3, e8-a3, e13/14-a3 and e19a3),*PML-RARA* [t(15;17) (q22;q21)],*CBFB-MYH11* [inv(16) (p13q22)],*AML1-ETO* [t(8:21) (q22:q22)],*E2A-PBX1* [t(1;19) (q23;p13)],*MLL-AF4* [t(4;11) (q21;q23)] and *TEL-AML* [t(12;21) (p13;q22)]. Furthermore, other pathogens tested include Influenza A H3N2, Influenza A H1N1 pdm09, Influenza B, *Haemophilus influenzae* type b, RSV (A and B), hMPV, CMV, HCV, EBV, BKV, *Plasmodium sp.*, Dengue virus, Chikungunya virus, VZV, Adenovirus, Rhinovirus, Enterovirus, hCoV (HKU1, 229E and NL63) and MERS-CoV, *Candida albicans, Streptococcus sp.*, *Mycoplasma pneumoniae*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Escherichia coli*, *Mycobacterium tuberculosis* (H37Rv), *Klebsiella pneumoniae*, *Enterococcus sp.*

4. Clinical Sensitivity and Specificity:

When compared to the Cepheid GeneXpert *BCR-ABL* Ultra, the *Gene*Path Dx *BCR-ABL* RT-PCR kit has **100% sensitivity** and **100% specificity**.

This kit is intended for use by experienced clinical laboratory personnel specifically instructed and trained in the techniques of real time PCR and *in vitro* diagnostic procedures. The required sample type for this assay is peripheral blood or bone marrow in EDTA vial.

For more information, please contact kit.sales@genepathdx.com.

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