



# XPert® BCR-ABL ULTRA

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| Test Reagent Kit   | Xpert® BCR-ABL Ultra  |
| Test Kit Catalog Number  | GXBCRABL-10   |
| Technology   | Nested RT-qPCR  |
| Targets  | BCR-ABL1 mRNA Transcript [e13a2 (b2a2), e14a2 (b3a2)]                 |
| Indication   | Quantitative Monitoring of BCR-ABL1 Transcript                        |
| Reports on the International Scale (IS)  | Yes   |
| Batch or On-Demand   | On-Demand   |
| Reagents on Board  | Yes   |
| Minimum Run Size   | 1   |
| Sample Extraction  | Automated/Integrated in Cartridge                                     |
| Pipetting Required   | Yes (Lysate preparation)  |
| Total Time to Result   | <2.5 hours  |
| Test Run Time  | 1 hour 47 minutes   |
| Off-board Sample Preparation Time  | <30 minutes   |
| Internal Controls  | Yes   |
| <i>Endogenous control</i>  | Yes (ABL1)  |
| <i>Probe Check Control (PCC)</i>   | Yes   |
| Software Required  | GeneXpert software v5.1 or higher<br>Xpertise software v6.6 or higher |
| Sensitivity (EDTA)   | 0.0030% (IS) / MR 4.52  |
| Specificity (Analytical)   | 100% for non-CML EDTA blood specimens                                 |
| Linear Range   | 0.0030%-55% (IS) / MR 4.52 – 0.26                                     |
| Precision (Analysis of Variance)   | Standard deviation of 0.15 near LoD (MR4)                             |
| Specimen Required  | Peripheral blood (EDTA)   |
| Sample Volume Required   | 4 mL  |
| Sample Stability   | 4° C for up to 72 hrs   |
| Sample Tested in Xpert Cartridge   | Lysate (quantity sufficient for 3 tests)                              |
| Alignment to WHO Reference Panel for BCR-ABL Standards using Secondary Standards | Yes with every lot  |
| Kit Storage  | 2-8° C  |
| Commercial Controls  | Yes, available via independent 3rd party<br>Contact Technical Support |



In Vitro Diagnostic Medical Device Not available in all countries.

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