Xpert® BCR-ABL Ultra UK NEQAS Cartridge Preparation Card

Before You Begin:

- Allow all Xpert BCR-ABL Ultra reagents and cartridges to come to room temperature (20-30°C) for 20 minutes.

1. **Incubate the UK NEQAS LI samples at room temperature for 5 minutes.**
2. **For each UK NEQAS LI sample vial, label two 50 mL conical tubes with the vial ID and mark one as tube (1) and the other as tube (2).**

Please use this document as a visual aid. To ensure that you understand the protocol, please read the Medical/ Scientific Affairs best practices. Refer to the package insert for detailed instructions, precautions, and warnings.

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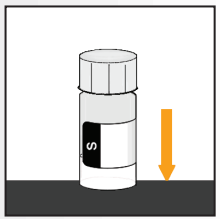
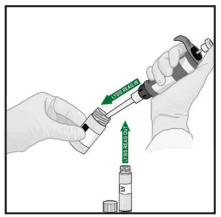
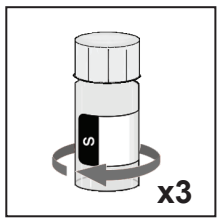
3 After completing the steps above, tap the vial gently to collect the lyophilized material at the bottom of the vial before opening.



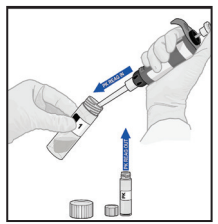
4 Add 1.5 mL Lysis Reagent to the lyophilized cells in the glass vial.



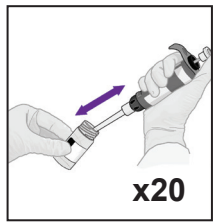
5 Gently swirl and leave for four minutes at room temperature. Repeat this step three times



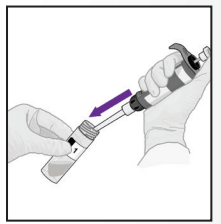
6 Add 100µL Proteinase K (PK) to conical tube (1).



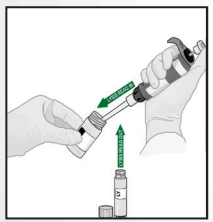
7a Set pipette to 0.8 mL and gently pipette 20 times to mix. Inspect vial closely to ensure all material is dissolved.



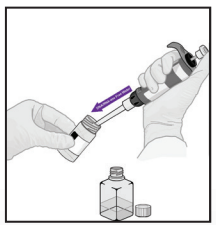
7b Transfer the cell resuspension to conical tube (1).



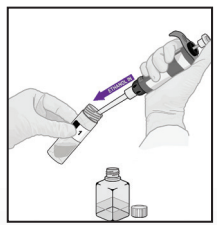
8 Add 1.0 mL Lysis Reagent to the glass vial. Repeatedly and gently pipet the Lysis Reagent to wash any cellular material from the walls/ bottom of the vial before transferring it into conical tube (1).



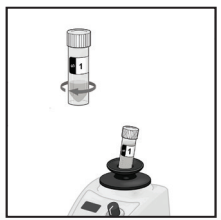
9 Repeat step 8 with 1.0 mL DNA/RNAse-free water and transfer into conical tube (1).



10 Add additional 3.0 mL DNA/ RNAse-free water to the conical tube (1).



11 Swirl conical tube (1) and vortex for 30 seconds.

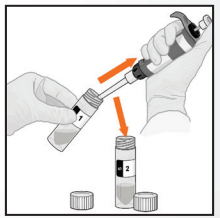


12 Incubate at RT for 20 minutes to allow the cells to lyse. During this incubation perform the following steps:

a. Add 0.45 mL DNA/RNAse-free water to a new conical tube (2).

b. Add 1.80 mL Lysis Reagent to conical tube (2).

13 Swirl the cell lysate in conical tube (1) before transferring 0.25 mL cell lysate to conical tube (2).



See reverse side for continued instructions.

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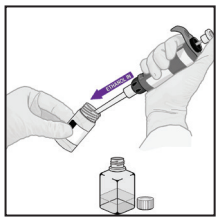
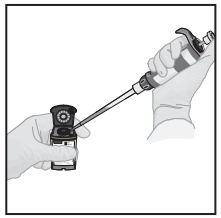
14 Vortex conical tube (2) for 20 seconds.

15a Add 2 mL Ethanol to conical tube (2).



15b Vortex for 30 seconds.

16 Add the entire sample to the cartridge.



17 Add the Wash Reagent.

18 Load the cartridge on to the GeneXpert® System (as described in the Package Insert).

NOTE: Retain the remaining lysate from conical tube (1) for retesting if required (following steps 13 -16). Store the lysate at -80 °C.
Before retesting, thaw out the retained lysate completely to room temperature and vortex for 10 seconds before use. If repeats are not required, discard extra lysate.

Disclaimer: This protocol was developed by Cepheid Oncology Research and Development and Medical and Scientific Affairs staff and describes an alternate sample preparation process for proficiency testing (PT) / external quality assurance (EQA) samples tested with the Xpert BCR-ABL Ultra test. This document is provided as a courtesy to Cepheid customers to provide guidance for participation in the UK NEQAS LI Major BCR-ABL1 Quantification Program. Cepheid does not endorse the testing of alternate specimen types (i.e., specimen types not included in the product labeling) with registered (FDA, CE, or other registration body) tests without proper validation, but recognizes the medical need of such testing for proficiency testing. If you choose to use Xpert BCR-ABL Ultra with alternate specimen types, it is your laboratory's responsibility to validate the assay in accordance with federal, state/province, and local laws. Additional testing of quality control samples and verification of other performance characteristics of the test also may need to be completed.testing for proficiency testing. If you choose to use Xpert BCR-ABL Ultra with alternate specimen types, it is your laboratory's responsibility to validate the assay in accordance with federal, state/province, and local laws. Additional testing of quality control samples and verification of other performance characteristics of the test also may need to be completed.

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