

Xpert BCR-ABL IS p210 Panel C206

INTENDED USE:

The Xpert BCR-ABL IS p210 Panel C206 is intended for use as a quality control material to monitor the *in vitro* quantitative detection of BCR-ABL1 translocation mRNA e14a2/b3a2 transcripts and the ABL1 endogenous control mRNA transcript when analyzed using the Xpert® BCR-ABL Ultra assay on Cepheid GeneXpert® Instrument Systems.

The Philadelphia chromosome, a translocation between the ABL1 gene on chromosome 9 and the BCR gene on chromosome 22, designated as t(9;22), generates the fusion gene BCR-ABL1 which is present in most chronic myelogenous leukemia patients. Quantitative monitoring of BCR-ABL1 transcripts in patient blood is an important tool for measuring response to therapy. In 2009, the World Health Organization (WHO) developed a panel of four BCR-ABL1 primary standards to establish an international scale (IS), a standardized method for reporting assay results as a ratio of fusion transcripts to control gene transcripts (%IS), useful to the harmonization of patient care across laboratories worldwide.^{1,2} The %IS can also be expressed as molecular response (MR), the log reduction from a standardized baseline of 100% on the IS. The Xpert BCR-ABL IS p210 Panel C206 is traceable to the WHO International Genetic Reference Panel for Quantitation of BCR-ABL Translocation (WHO Reference Panel), NIBSC code 09/138, and designed for use with the Xpert BCR-ABL Ultra assay which reports on the international scale.

PRODUCT SUMMARY and PRINCIPLE:

Xpert BCR-ABL IS p210 Panel C206 consists of three components. Each component contains an increasing concentration of BCR-ABL1 (e14a2/b3a2) RNA transcript mixed with a fixed concentration of ABL1 RNA transcript to produce three levels, 0%IS, 0.01%IS, and 1%IS. The %IS values traceable to WHO International Genetic Reference Panel, NIBSC code 09/138, are assigned to each lot of Xpert BCR-ABL IS p210 Panel C206 by following NIBSC Instructions for Use³.

COMPOSITION:

Xpert BCR-ABL IS p210 Panel C206 is comprised of 12 bottles, 4 bottles of each %IS level. The C206 0.01%IS, and 1%IS levels contain 4 mL of synthetic BCR-ABL1 RNA transcript and synthetic ABL1 control gene RNA transcript, suspended in a stabilizing matrix with a non-infectious solution of buffers and preservatives. The 0%IS level contains ABL1 RNA transcript suspended in a stabilizing matrix with a non-infectious solution of buffers and preservatives.

STORAGE and STABILITY:

Xpert BCR-ABL IS p210 Panel C206 should be stored at -25°C to -15°C. Unopened Xpert BCR-ABL IS p210 Panel C206 material is stable through the expiration date printed on the kit label when consistently stored frozen. Discard after use according to your local and federal regulations.

INSTRUCTION FOR USE:

1. Allow the Xpert BCR-ABL IS p210 Panel C206 component to be tested to come completely to room temperature (18°C – 25°C), approximately 30 minutes, until bottles are warm to the touch.
2. Immediately before pipetting, thoroughly mix the C206 panel component by inverting 8 times followed by 2 pulse vortexes, 2-3 seconds each at maximum speed.
3. Add 4mL of the C206 panel component to 100µL of Proteinase K in a conical tube, as you would a blood specimen.
4. Continue with the assay procedure according to manufacturer's instructions.
5. Discard after use according to local and federal regulations.

PRECAUTIONS and WARNINGS:

- Use the control as provided. Do not dilute or transfer to another storage tube.
- This product is intended for *in vitro* diagnostic use only.
- This product is slightly cloudy in appearance.
- This product does not contain any biological material of human or animal origin. Universal Precautions are NOT required when handling this product.
- Xpert BCR-ABL IS p210 Panel C206 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

EXPECTED VALUES:

Locate the appropriate WHO-traceable %IS/MR values assigned to your lot of Xpert BCR-ABL IS p210 Panel C206 on the unique Certificate of Analysis provided with each shipment of Xpert BCR-ABL IS p210 Panel C206. It is important to notice that the WHO-traceable values were assigned by testing the WHO International Reference Panel and the Xpert BCR-ABL IS p210 Panel C206 with one lot of Xpert BCR-ABL Ultra cartridges. **Each laboratory should establish their own %IS ranges.** Please refer to assay manufacturer for expected assay performance specifications.

Routine use of reference materials that are consistent lot to lot assists the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system.

ORDERING INFORMATION:

Xpert BCR-ABL IS p210 Panel C206

Part Number: C206

Kit Contains: 12 bottles x 4mL

4 each of 0%IS, 0.01%IS, and 1%IS

References

¹Branford S et al. Desirable performance characteristics for BCR-ABL measurement on an international reporting scale to allow consistent interpretation of individual patient response and comparison of response rates between clinical trials. *Blood* 2008, 112:3330-38

²White HE et al. Establishment of the first World Health Organization International Genetic Reference Panel for quantitation of BCR-ABL mRNA. *Blood* 2010, 116:e111-117

³1st WHO International Genetic Reference Panel for quantitation of BCR-ABL translocation by RQ-PCR NIBSC code: 09/138 Instructions for use (Version 9.0, Dated 22/10/2020)