



## Xpert BCR-ABL1 p190 0%

### INTENDED USE:

The Xpert BCR-ABL1 p190 0% is intended for use as an assayed external quality control to monitor the *in vitro* quantitative detection of the p190 BCR-ABL1 translocation mRNA transcript and the ABL1 endogenous control mRNA transcript when analyzed using the Xpert® BCR-ABL Ultra p190 assay on Cepheid GeneXpert® 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 (CML) patients and “Philadelphia positive” acute lymphoblastic leukemia of B-cell lineage (Ph<sup>+</sup>ALL)<sup>1</sup>. Depending on the translocation breakpoint in BCR, different BCR-ABL protein isoforms are expressed, which all contain exons 2-11 of the ABL1 gene, but differ in the length of their BCR component. The most common BCR-ABL isoforms are the major p210 and minor p190 translocations, corresponding to a 210kD protein and a 190kD protein, respectively<sup>2</sup>. The major p210 BCR-ABL1 translocation is the hallmark of CML, whereas the minor p190 BCR-ABL1 occurs in the majority of B-cell acute lymphoblastic leukemia patients<sup>3</sup>. Quantitative monitoring of BCR-ABL1 transcripts in patient blood is an important tool for measuring response to therapy.

### PRODUCT SUMMARY and PRINCIPLE:

The Xpert BCR-ABL1 p190 0% is composed of one level, Xpert BCR-ABL1 p190 0%, which contains synthetic RNA transcripts of control gene ABL1. This control is designed to represent a sample with no fusion gene BCR-ABL1 present when analyzed on the GeneXpert system with the Xpert BCR-ABL Ultra p190 assay. Xpert BCR-ABL1 p190 0% is also a component of Xpert BCR-ABL1 p190 Control Panel C183, part number C183.

Quality controls can be used for routine monitoring of test systems, validation, verification, proficiency assessment, and training procedures. Quality controls that are consistent from lot to lot assist the laboratory in identifying shifts, trends and increased frequency of random errors caused by variations in the test system, such as failing reagents or malfunctioning equipment. Early investigation can prevent failed assay runs.

### COMPOSITION:

Xpert BCR-ABL1 p190 0% contains 5 single-use bottles of Xpert BCR-ABL1 p190 0% consisting of synthetic ABL1 control gene transcript suspended in a stabilizing matrix with a non-infectious solution of buffers and preservatives.

#### References

- <sup>1</sup> Chan LC, Karhi KK, Rayter SI, Heisterkamp N, Eridani S, Powles R, Lawler SD, Groffen J, Foulkes JG, Greaves MF, Wiedemann LM. A novel *abl* protein expressed in Philadelphia chromosome positive acute lymphoblastic leukaemia. *Nature*. 1987;325:635-637.  
<sup>2</sup> Faenstein E, Marcelle C, Rosner A, Canaani E, Gale RP, Drezzen O, Smith SD, Croce CM. A new fused transcript in Philadelphia chromosome positive acute lymphocytic leukaemia. *Nature*. 1987; 330:386-388.  
<sup>3</sup> Shaoguang, L et al. The P190, P210 and P230 Forms of the BCR/ABL Oncogene Induce a Similar Chronic Myeloid Leukemia-like Syndrome in Mice but Have Different Lymphoid Leukemogenic Activity. *Blood* 2008, 112:3330-38

### STORAGE and STABILITY:

Xpert BCR-ABL1 p190 0% should be stored at -25°C to -15°C. Unopened material is stable through the expiration date printed on the kit label when consistently stored frozen. Xpert BCR-ABL1 p190 0% is for single-use only. Discard after use according to your local and federal regulations.

### PRECAUTIONS, WARNINGS, and LIMITATIONS:

- This product is intended for *in vitro* analytical testing and is provided for Research Use Only. It is not for use in diagnostic procedures.
- 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-ABL1 p190 0% cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.
- Quality control materials should be used in accordance with local, state, and federal regulations and accreditation requirements.

### INSTRUCTION FOR USE:

1. Allow the Xpert BCR-ABL1 p190 0% component to be tested to come completely to room temperature (18°C to 25°C), approximately 30 minutes, until bottles are warm to the touch.
2. Immediately before pipetting, thoroughly mix the control bottle by inverting 8 times followed by 2 pulse vortexes, 2-3 seconds each at maximum speed.
3. Add 4mL of the control sample 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.

### EXPECTED VALUES:

The expected result of Xpert BCR-ABL1 p190 0% when tested with the Xpert BCR-ABL Ultra p190 assay on the Cepheid GeneXpert system is: BCR-ABL p190 Not Detected [Sufficient ABL transcript].

| Control                | Test Result                                                            |
|------------------------|------------------------------------------------------------------------|
| Xpert BCR-ABL1 p190 0% | <b>BCR-ABL p190 Not Detected</b><br><b>[Sufficient ABL transcript]</b> |

### ORDERING INFORMATION:

Xpert BCR-ABL1 p190 0%

**Part Number: C17612-5**

Kit contains: 5 bottles x 4mL