

INTROL® BCR-ABL1 p190 Control Panel

INTENDED USE:

The INTROL BCR-ABL1 p190 Control Panel is intended for use as reference material 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® 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 (CML) patients and “Philadelphia positive” acute lymphoblastic leukemia of B-cell lineage (Ph⁺ALL)¹. 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, respectively². 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 patients³. Quantitative monitoring of BCR-ABL1 transcripts in patient blood is an important tool for measuring response to therapy.

PRODUCT SUMMARY and PRINCIPLE:

The INTROL BCR-ABL1 p190 Control Panel consists of 5 components. Each component contains an increasing concentration of BCR-ABL1 (e1a2) RNA transcript mixed with a fixed concentration of ABL1 RNA transcript to produce 5 levels, 0%, 0.02%, 0.1%, 1%, and 10%, with the 0% level containing ABL1 RNA transcript only. The ratio of e1a2 RNA to ABL1 RNA has been confirmed by digital PCR.

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.

COMPOSITION:

INTROL BCR-ABL1 p190 Control Panel is comprised of 10 single-use bottles, 2 bottles of each % ratio level. Each bottle contains 4 mL of synthetic RNA transcripts, suspended in a stabilizing matrix with a non-infectious solution of buffers and preservatives. Level 0% contains ABL1 RNA transcript only. Levels 0.02%, 0.1%, 1%, and 10% contain ratios of BCR-ABL1 RNA transcript and ABL1 RNA transcript.

STORAGE and STABILITY:

INTROL BCR-ABL1 p190 Control Panel 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. INTROL BCR-ABL1 p190 controls are for single use. Discard after use according to your local and federal regulations.

References

- ¹ 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.
- ² Fainstein E, Marcelle C, Rosner A, Cnaan E, Gale RP, Drazzen O, Smith SD, Croce CM. A new fused transcript in Philadelphia chromosome positive acute lymphocytic leukaemia. *Nature*. 1987; 330:386-388.
- ³ 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

PRECAUTIONS and WARNINGS:

- Use the control as provided. Do not dilute or transfer to another storage tube.
- This product is intended for *in vitro* analytical testing and is provided for Research Use Only, 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.
- INTROL BCR-ABL1 p190 Control Panel cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

INSTRUCTION FOR USE:

1. Allow the INTROL BCR-ABL1 p190 controls 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 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:

Table 1 lists an example of the results when the INTROL BCR-ABL1 p190 controls are analyzed by the Xpert BCR-ABL Ultra p190 assay on the Cepheid GeneXpert Instrument. The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics and ranges for each INTROL BCR-ABL1 p190 level.

Table 1: Example of Results for INTROL BCR-ABL1 p190 Controls when Tested on a GeneXpert Instrument System.

INTROL BCR-ABL1 p190 Component	Test Result
INTROL BCR-ABL1 p190 0%	BCR-ABL p190 Not Detected [Sufficient ABL transcript]
INTROL BCR-ABL1 p190 0.02%	BCR-ABL p190 Detected [0.019%]
INTROL BCR-ABL1 p190 0.1%	BCR-ABL p190 Detected [0.110%]
INTROL BCR-ABL1 p190 1%	BCR-ABL p190 Detected [1.25%]
INTROL BCR-ABL1 p190 10%	BCR-ABL p190 Detected [8.32%]

ORDERING INFORMATION:

INTROL BCR-ABL1 p190 Control Panel

Part Number: C183

Kit contains: 10 bottles x 4mL

2 of each % Level (0%, 0.02%, 0.1%, 1% and 10%)