ipsogen® BCR-ABL1 Mbcr IS-MMR Kits CE

For quantification of BCR-ABL1 Mbcr and results reporting on the international scale

ipsogen BCR-ABL1 Mbcr IS-MMR Kits are in vitro diagnostic kits for real-time PCR on the Rotor-Gene® Q and other real-time PCR instruments. The kits provide reagents optimized for reliable and sensitive detection and quantification of BCR-ABL1 p210 b2a2 or b3a2 transcripts in bone marrow, or peripheral blood samples of acute lymphoblastic leukemia (ALL), or chronic myeloid leukemia (CML) patients previously diagnosed with a BCR-ABL1 Mbcr fusion gene event. The test is intended to evaluate the level of molecular response; results can be used for minimal residual disease (MRD) follow-up.

ipsogen BCR-ABL1 Mbcr IS-MMR Kits provide:

- Results on the international scale (IS) and MMR reporting
- One IS-MMR calibrator per run to prevent drifting
- High reliability using EAC technology and single plasmid standards
- Compliance with EU IVD Directive 98/79/EC
- Easy workflow with ready-to-use solutions

Accurate quantification of BCR-ABL1 Mbcr using real-time PCR

ipsogen BCR-ABL1 Mbcr IS-MMR Kits are ready-to-use kits for the quantification of BCR-ABL1 p210 b2a2 or b3a2 transcripts using real-time PCR. The kits are based on the amplification and detection of specific BCR-ABL1 p210 b2a2 or b3a2 transcripts, relative to ABL control gene expression, in total RNA.

Highly sensitive assay

To ensure highest sensitivity, ipsogen BCR-ABL1 Mbcr IS-MMR Kits have been optimized to detect low levels of BCR-ABL1 p210 b2a2 or b3a2 transcripts and ABL control gene transcript (Figures 1 and 2). The sensitivity has a limit of detection (LOD) of 0.0069.

![Figure 1. Accurate detection of Mbcr single plasmid standards, high positive RNA control, and IS-MMR calibrator. Mbcr single plasmid standards (SP1-SP6), 10^1, 10^2, 10^3, 10^4, and 10^5 copies/5 µl.](image)

![Figure 2. Accurate detection of ABL single plasmid standards, high positive RNA control, and IS-MMR calibrator. ABL single plasmid standards (SP3-SP6), 10^1, 10^2, 10^3, and 10^4 copies/5 µl.](image)
Highly specific and reproducible assay

Each *ipsogen* BCR-ABL1 Mbcr IS-MMR Kit provides 4 standard dilutions for ABL and 5 standard dilutions for Mbcr. Use of a single plasmid for BCR-ABL1 and ABL enables reproducible quantification of transcripts and limits variability. Primers and probe sets are designed according to Europe Against Cancer (EAC) recommendations (Figures 3 and 4).

The kits also include an IS-MMR calibrator allowing conversion of results to the international scale for accurate measurement of molecular response and major molecular response (MMR) status reporting (Figure 5). A high positive RNA control is also included to monitor the reverse transcription and amplification steps of ABL and BCR-ABL1 Mbcr during transcript quantification. Furthermore, the *ipsogen* BCR-ABL1 Mbcr IS-MMR DX Kit includes reagents for reverse transcription-PCR and real-time PCR.

Figure 3. Abl control gene transcript primers and probe design according to EAC recommendations.

Figure 4. BCR-ABL1 fusion gene transcripts primers and probe design according to EAC recommendations.

Figure 5. *ipsogen* BCR-ABL1 Mbcr IS-MMR Kit CE components.
Optimized IS-MMR calibrator development

The IS-MMR calibrator is manufactured under defined specifications in accordance with an ISO 13485 quality system and an IS-MMR calibrator value is assigned after quality control with the RM II panel for each new batch (Figure 6). The IS-MMR calibrator development is fully traceable from WHO certified primary international reference material (1).

Simple and easy workflow

Analysis of BCR-ABL1 p210 b2a2 or b3a2 and ABL transcripts comprises initial reverse transcription of total RNA of samples into cDNA followed by the amplification of cDNA by real-time PCR with ipsogen BCR-ABL1 Mbcr IS-MMR Kits.

References

### Ordering Information

<table>
<thead>
<tr>
<th>Product</th>
<th>Contents</th>
<th>Cat. no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ipsogen BCR-ABL1 Mbcr IS-MMR DX Kit (24) CE</td>
<td>For 24 reactions: Reverse transcriptase, 5x RT buffer, dNTP mix, Random primers, RNase Inhibitor, DTT, High Positive RNA Control, IS-MMR Calibrator, Mbcr and ABL Single Plasmid Standards, Primers and Probe Mix ABL, Primers and Probe Mix BCR-ABL1 Mbcr Fusion Gene, qPCR Master mix, ROX™ I fluorescent dye, ROX II fluorescent dye</td>
<td>670823</td>
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<tr>
<td>ipsogen BCR-ABL1 Mbcr IS-MMR Kit (24) CE</td>
<td>For 24 reactions: High Positive RNA Control, IS-MMR Calibrator, Mbcr and ABL Single Plasmid Standards, Primers and Probe Mix ABL, Primers and Probe Mix BCR-ABL1 Mbcr Fusion Gene</td>
<td>670723</td>
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</tbody>
</table>

### Related products

| ipsogen BCR-ABL1 Mbcr Controls Kit | Cell lines with negative, high, and low positive expression of the BCR-ABL1 Mbcr fusion gene | 670191 |
| Rotor-Gene Q MDx 5plex HRM System | Real-time PCR cycler and High Resolution Melt analyzer with 5 channels (green, yellow, orange, red, crimson) plus HRM channel, laptop computer, software, accessories, 1-year warranty on parts and labor, installation and training | 9002033 |
| ipsogen RT Kit (33) CE | For 33 reactions: Reverse transcriptase, 5x RT buffer, dNTP mix, Random primer, RNase Inhibitor, DTT | 679923 |
| RNeasy® Mini Kit (50) | For 50 RNA preps: 50 RNeasy Mini Spin Columns, Collection Tubes (1.5 ml and 2 ml), RNase-free Reagents and Buffers | 74104 |

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