BCR-ABL1 p190 Quantification Services

**TEST DESCRIPTION**

MolecularMD e1a2 (p190) One-Step BCR-ABL Real-time PCR Quantification assay is intended for the accurate quantitation of BCR-ABL1 e1a2 transcripts in bone marrow or peripheral blood samples of ALL or CML patients previously diagnosed with a Philadelphia positive (Ph+) m-bcr (e1a2) Fusion Gene event.

MolecularMD proprietary primers for the e1a2 quantification assay target reference gene ABL1 and BCR-ABL1 p190 fusion transcripts. Detectec p190 BCR-ABL1 transcripts are reported as a ratio of BCR-ABL/ABL.

The MolecularMD e1a2 BCR-ABL1 assay allows residual disease monitoring for patients on targeted kinase inhibitor therapy. Cumulative transcript level results graphically presented in the physician report allow monitoring of patient trends.

**CLINICAL UTILITY**

Targeted BCR-ABL1 kinase inhibitors are an effective first-line treatment for the majority of CML and Ph+ ALL patients. Serial analysis of BCR-ABL1 levels is an effective method for monitoring treatment efficacy for the majority of these patients.

**ASSAY SPECIFICATIONS**

<table>
<thead>
<tr>
<th>Methodology:</th>
<th>One-step quantitative real-time PCR</th>
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</thead>
<tbody>
<tr>
<td>BCR-ABL/ABL1 Calibrators:</td>
<td>3e^6, 3e^5, 3e^4, 3e^3, 3e^2, 3e^1, 3e^0 series of calibrators generate BCR-ABL and ABL standard curves spanning a 6-log dynamic range</td>
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<td>e1a2 RNA Controls:</td>
<td>BCR-ABL high, low, and negative controls</td>
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<td>Reporting:</td>
<td>• BCR-ABL/ABL1 ratio (raw) • BCR-ABL/ABL1 ratio (%) • BCR-ABL copy number • ABL1 copy number • Graphed results of prior quantification assay runs (trends)</td>
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**DISEASE RELEVANCE**

- Chronic myelogenous leukemia (CML)
- Ph+ acute lymphocytic leukemia (ALL)

**DRUG RELEVANCE**

- ABL1 tyrosine kinase inhibitors

**RELATED ASSAYS**

- b2/b3a2 BCR-ABL1 RT-qPCR
- BCR-ABL1 mutation analysis (p210 and p190)

**EXPERIENCE**

MolecularMD’s centralized CLIA-certified and CAP-accredited molecular diagnostics laboratory has a proven track record in supporting pivotal international clinical research programs. We are a preferred provider of specialty molecular diagnostics services to pharmaceutical and biotech drug developers, offering assays that are rigorously validated to provide rapid and reproducible results that enable prompt clinical decision-making relevant for both solid tumors and hematological malignancies. Our experience and commitment to quality make MolecularMD a leader in reference lab services and an optimal partner for companion diagnostics development.
**Test Information:**

**e1a2 (p190) BCR-ABL PCR Results**

**Method:**
- e1a2 BCR-ABL Quant.
- QRT-PCR

**Test Results:**
- **BCR-ABL/ABL (raw%):** 0.0038 (0.38%)
- **ABL Copies:** 36949
- **BCR-ABL Copies:** 139

**Interpretation:**
- **e1a2 BCR-ABL Quantitation Results:** The ratio of BCR-ABL/ABL is 0.0038 (0.38%).

The ABL copy number indicates that the quality of the RNA was adequate to accurately report this result.

**Cumulative Results: QRT-PCR Trend**

[Graph showing cumulative results]

For more information on BCR-ABL1 Quantification Services, email bd@molecularmd.com or call +1 877-459-4979