

# BCR-ABL1 Gene Fusion Analysis

These tests are intended for the qualitative and quantitative detection of BCR-ABL1 fusion gene transcripts Major (M), minor (m), and micro ( $\mu$ ) in bone marrow or peripheral blood samples of CML or ALL or AML using Real-Time PCR platform.

The BCR-ABL1 gene fusion is a result of a reciprocal translocation between chromosome 9 and 22 [t(9;22)(q34;q11.2)] and it is a hallmark event which has been detected in 90-95% of Chronic Myeloid Leukemia (CML), 20% of adults and 5% of children acute lymphoblastic leukemia (ALL) patients and 2% of adults acute myelogenous leukemia (AML) patients.

## BCR-ABL1 Qualitative gene fusion analysis (Major, Minor & Micro)

Qualitative detection and differentiation of BCR-ABL1 fusion transcript helps clinician in treatment plan. As a prognostic marker in ALL patients, presence of BCR-ABL1 gene rearrangement is associated with poor prognosis.



## BCR-ABL1 Quantitative (International Scale) gene fusion analysis (Major transcript)

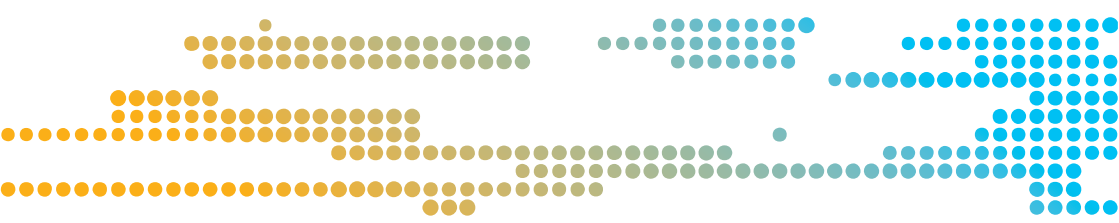
Upon treatment with TKI therapy, the CML disease is known to go through three different phases of response assessment, namely hematologic, cytogenetic and molecular remission that corresponds to decreasing levels of BCR-ABL1 transcript as well as the leukemic cells. Presence of BCR-ABL1 transcript  $\leq$  0.001% (IS) correlates with achievement of DMR with 5-log reduction from IRIS baseline.

This test can also be used for the assessment of molecular response up to 5-log reduction (deep molecular response) and for minimal residual disease.

### Additional information:

- The test uses the lot specific correction factor (CF) to report the BCR-ABL1 (major) transcript levels in International Scale (IS %; to avoid interlaboratory result variation).
- IS scale have not been established for the p190 (minor transcript) and p230 (micro transcript) BCR-ABL1 fusion gene.
- Limit of Detection (LOD) of the test is 1.76 copies of BCR-ABL1 transcript (Major (IS), minor, micro).

MedGenome offers	Test Sample requirements	Required clinical Details	TAT
BCR-ABL qualitative gene fusion analysis (Major, Minor & Micro) (MGM173)	 Peripheral blood OR 	<ul style="list-style-type: none"> <li>• Clinical diagnosis to be mentioned on TRF</li> <li>• Bone Marrow aspiration report</li> </ul>	4 Working days
BCR-ABL quantitative (International Scale) gene fusion analysis (MGM174)	Bone marrow aspirate  (2 - 8° C)		5 Working Days



### Get in touch