

BCR-ABL GENE REARRANGEMENT, PCR QUANTITATIVE

BCR-ABL GENE REARRANGEMENT, PCR QUANTITATIVE (Real Time PCR)	
BCR-ABL gene rearrangement	%
Type of Translocation	
BCR-ABL International Scale Normalized copy number (IS-NCN)	

Interpretation

Significance of International scale

IS-NCN	REMARKS
≤ 0.05	Major Molecular Response
0.05 - 0.15	Gray zone around Major Molecular Response cutoff, inconclusive result
≥ 0.15	No Major Molecular Response

Note:

1. Sensitivity of the assay is 0.01% when copies of ABL detected is 100,000
2. Limit of detection is 10 copies of BCR-ABL fusion gene transcripts per PCR
3. This is an in-house developed assay designed as per EAC (Europe Against Cancer) protocol
4. This test detects Major (M) gene rearrangements namely- e13a2 & e14a2 and Minor (m) gene arrangement e1a2. This test does not detect micro gene rearrangement e19a2.
5. Test conducted on Whole blood / Bone Marrow.
6. This test gives percentage of BCR-ABL fusion gene detected with respect to the ABL transcript present as well as the International scale value to harmonize the result.

Comments

Chronic Myeloid Leukemia (CML) is the commonest myeloproliferative neoplasm and possibly the commonest adult leukemia in India. This clonal stem cell disorder is characterized by a proliferation of myeloid cells at all stages of differentiation and the t(9:22) (q34;q11) leading to formation of BCR-ABL fusion gene. Cytogenetic and molecular studies are vital for the diagnosis of CML by using detection procedures for Philadelphia chromosome. The abnormality is present in over 95% patients of CML while remainder 5% have complex or variant translocations involving additional chromosomes. Major gene rearrangements are detected in CML while minor gene arrangement may be detected in ALL.

Uses

- To monitor therapy in CML patients. A 3 log reduction in BCR-ABL gene rearrangement is associated with good prognosis.
- Monitoring of Minimal Residual Disease (MRD).
- As a prognostic marker in ALL patients. Presence of BCR-ABL gene rearrangement is associated with poor prognosis.

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