

Mr. SATINDER

AMBALA, CHEMBUR Tel No: 8607344999

PIN No: 133001

PID NO: P542100436044

Age: 25.0 Year(s) Sex: Male

Reference: Dr.VINAY CHOPRA VID: 54213320015787

Sample Collected At: Dr vinay kumar chopra

Kos diagnostic lab, 6349/i, nicholson road,

ambala cantt, hry 133001.

PROCESSING LOCATION: - Metropolis Healthcare Ltd, Unit No. 409- 416, 4th Floor, Commercial Building-1, Kohinoor

Mall, Mumbai-70

Registered On:

12/04/2021 07:20 PM Collected On:

13/04/2021 11:53AM Reported On:

22/04/2021 02:07 PM

BCR-ABL IS (International Scale) Transcript fusion Quantification

Test Principle Real Time PCR

Equipment Rotor Gene 3000 from Corbett Research, Australia

Specimen BLOOD

Result :

M-BCR-ABL IS count %	5.6103 %
ABL (Control Gene)	17024 copies

Comments: KINDLY CORELATE WITH THE CLINICAL FINDINGS, CBC FINDINGS, PREVIOUS BCR ABL QUANTIFICATION REPORTS AND TREATMENT HISTORY.

Result Interpretation:

- The international reporting scale (IS) has been established which expresses detectable disease as a percentage (0.1 % is corresponds to MMR) and is essentially identical to that used in the IRIS trial to achieve Major molecular response (MMR).
- BCR-ABL transcript quantification is expressed as a % of the control gene i.e., ABL. The sample showing amplification curve for both BCR/ABL transcript fusion gene (FG) and (CG) are considered as positive for the test and are reported as a % expression of BCR/ABL over ABL.
- In the absence of amplification curve for the CG or copies < 10000, the test is reported as invalid, denoting degradation of
- This test is directed for the quantification of Major breakpoint at e14a2 and e13a2 corresponding p210 transcript, which is found in 95 % of CML patients.

Reference Range of Major Molecular Response (MMR) Status:

IS BCR-ABL/ABL %	Log Reduction	Response
IS BCR-ABL/ABL% < 0.001	5.0	Deep Molecular Response (DMR)
IS BCR-ABL/ABL% < 0.0032	4.5	Deep Molecular Response (DMR)
IS BCR-ABL/ABL% < 0.01	4	Deep Molecular Response (DMR)
IS BCR-ABL/ABL% < 0.1	3	Major Molecular Response (MMR)
0.1 < IS BCR-ABL/ABL% < 0.15	-	Around the MMR cut -off
IS BCR-ABL/ABL% > 0.15	-	No Major molecular Response

Dr. Niranjan Patil

MD(Micro)

HOD - Microbiology & Molecular Biology





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Clinical Background:

Quantitative analysis of BCR/ABL transcript level by real time PCR should ideally be performed before the start of the therapy in order to determine the baseline value and for minimal residual disease (MRD) estimation.

- Since the introduction of BCR-ABL kinase inhibitor therapy, molecular monitoring after
- achieving complete cytogenetic response (CCR) post- initiation therapy has become particularly relevant & crucial.
- The BCR-ABL gene translocation or t(9;22) is found in more than 95% CML patients, 5% of paediatric ALL-B CALLA positive and 15-30% of adult ALL-B CALLA positive patients. This genetic aberration is a balanced reciprocal translocation between ABL gene on chromosome 9 and BCR gene on chromosome 22. This test is performed for the quantitative detection and differentiation of BCR-ABL fusion gene transcripts, Major (M), minor (m) and micro in bone marrow or peripheral blood samples of ALL or CML using real time PCR. Follow-up is recommended, if clinically indicated. A repeat testing after 6 months is additionally recommended.
- The lower limit of BCR-ABL transcript detection in the assay is dependent on the quality of RNA obtained and the cellularity of the sample. Since genetic variation and other problems can affect the accuracy of PCR based testing, the result should always be interpreted in light of clinical data.

Limitation of Assay:

- Other Transcripts p230 and p190 cannot be detected by this assay.
- PCR is a highly sensitive method; common reasons for paradoxical results are contamination during specimen collection, selection of inappropriate specimens and inherent PCR inhibitors in the specimen.

- BACCARANI et al., European LeukemiaNet recommendations for the management of chronic myeloid
- leukemia: 2013, BLOOD, 8 AUGUST 2013, VOLUME 122, NUMBER 6
- ChaoJie Zhen and Y. Lynn Wang, Molecular Monitoring of Chronic Myeloid Leukemia: International
- Standardization of BCR-ABL1 Quantitation, J Mol Diagn 2013, 15: 556e564

-- End of Report --

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