ISO 9001 : 2008 CERTIFIED LAB

KOS Diagnostic Lab
(A Unit of KOS Healthcare)

KOS™
EXCELLENCE IN HEALTHCARE & DIAGNOSTICS

Dr. Vinay Chopra
MD (Pathology & Microbiology)
Chairman & Consultant Pathologist

Dr. Yugam Chopra
MD (Pathology)
CEO & Consultant Pathologist

LABORATORY REPORT

Name	: **Mr SUMIT**	Sex/Age	: **Male / 24 Years**	Case ID	: **40821600514**
Ref. By	: DR. VINAY CHOPRA	Dis. At	:	Pt. ID	:
Bill. Loc.	: KOS DIAGNOSTIC LAB			Pt. Loc	:
Reg Date and Time	: 04-Aug-2024 09:33	Sample Type	: Whole Blood EDTA	Mobile No.	:
Sample Date and Time	: 04-Aug-2024 09:33	Sample Coll. By	: non	Ref Id1	:
Report Date and Time	: 08-Aug-2024 17:12	Acc. Remarks	: -	Ref Id2	:

TEST	RESULTS	UNIT	BIOLOGICAL REF RANGE	REMARKS
BCR-ABL1 Fusion Transcript (International Scale) Quantitative p210				
BCR-ABL1 Copy number (p210: e13a2 or e14a2)	25			
ABL1 Copy number	166421			
Result For BCR-ABL1 Fusion Gene Transcript	0.0150			
International Scale Normalized Copy Number (%)	0.017			

METHODOLOGY:
The assay involves extraction of RNA from EDTA whole blood or bone marrow followed by reverse transcription Realtime PCR for quantitative assessment of BCR-ABL1 transcripts.

BACKGROUND:
The Philadelphia chromosome, a reciprocal translocation between the long arms of chromosome 9 & 22, is found in >90 % CML, 15-20% adults ALL and 7% childhood ALL patients and 1-2% with AML. Cases of chronic myeloid leukemia, BCR-ABL1 positive (CML) and a subset of cases of acute lymphoblastic leukemia (ALL) harbor the t(9;22)(q34;q11) breakpoint, resulting in the BCR-ABL1 p210 fusion oncogene (Philadelphia chromosome).

INTERPRETATION:
This test gives percentage of BCR-ABL1 fusion gene detected with respect to the ABL1 transcript present as well as the International scale value to harmonize the result.
Positive: BCR-ABL1 fusion transcript (p210) is detected and quantitative ratio is provided (normalized copy number). Result is also reported in terms of BCR-ABL1 international scale (IS).
Not detected: No BCR-ABL1 fusion transcripts (p210) detected.
Does not exclude BCR-ABL1 fusion transcripts (p210) below the test limit of detection and the other fusion transcripts that are not detected by this test (for eg. p190, p205, p230, etc).

SIGNIFICANCE OF INTERNATIONAL SCALE:
This report is normalized to the International Scale which enables standardization between labs worldwide. This BCR-ABL1 report should not be compared to any Non IS scale report. The IS scale is assessed by comparison of the internal results of the lab with those expected from WHO calibrated controls. The above IS standardization has been performed only for the e13a2 and the e14a2.The reproducibility of this assay is such that results within 0.5 log should be considered equivalent.

TABLE: MONITORING MOLECULAR RESPONSE

Case	IS-NCN% of sample	ABL1 Copies	MMR/DMR status	Remarks
1	> 0.1%	> 10000	No MMR	Major Molecular Response not achieved
2	=0.1%	> 10000	MMR (MR3)	Major Molecular Response achieved with 3-log reduction from IRIS baseline
3	= 0.01%	10000-31999	DMR-4	Deep Molecular Response achieved with 4-log reduction from IRIS baseline
4	= 0.0032%	32000- 99999	DMR-4.5	Deep Molecular Response achieved with 4.5-log reduction from IRIS baseline

Note:(LL-VeryLow,L-Low,H-High,HH-VeryHigh ,A-Abnormal)

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MD Path, PDF Lab. Haemat.,
PDF Mol. Haemonc.

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5	= 0.001%	= 100000	DMR-5	Deep Molecular Response achieved with 5-log reduction from IRIS baseline

CLINICAL UTILITY:
Cases of chronic myeloid leukemia, BCR-ABL1 positive (CML) and a subset of cases of acute lymphoblastic leukemia (ALL) harbor the t(9;22)(q34;q11) breakpoint, resulting in the BCR-ABL1 p210 fusion oncogene (Philadelphia chromosome). For CML patients, the introduction of tyrosine kinase inhibitor therapy has greatly improved clinical outcome. Quantitative PCR (qPCR)-based monitoring is critical for the assessment of important treatment milestones, such as major molecular response (MMR), and is also helpful for the early detection of emerging drug resistance. Nearly all CML patients and a subset of Philadelphia chromosome positive ALL patients exhibit the p210 BCR-ABL1 fusion resulting from a translocation between BCR exons 13 or 14 and ABL1 exon 2 (e13a2, e14a2). Test is conducted on Whole blood/Bone Marrow. The analytical sensitivity of this assay has been determined at 0.01%.

LIMITATION:
a. The assay does not detect other BCR-ABL1 mRNA types, including the e1/a2 transcript (p190 protein) that is commonly present in acute lymphoblastic leukemia.
b. This test detects only the fusion protein p210 and does not detect other variants.
c. The results of this test are highly dependent on the sampling technique employed, sample type, cold-chain maintenance and clinical condition.
d. In case of Presence of PCR inhibitors, low WBC count or receipt of sample without maintaining the cold chain or after 48 hours, it may result in low ABL1 copies or they may not amplify due to these reasons, repeat sample may be needed. 95% of the false-negative result is due to deterioration of RNA and in such cases, please correlate clinically.
e. There is a possibility of background RNA contamination resulting from a preanalytical issue or from in lab environment which may result in a false positive report.
f. In cases of high clinical suspicion, it is advised to repeat the test after 3 months to check for a rising titre.
g. The assay performance characteristics for this test are determined by Supratech Micropath Private Limited (STMPL) which is used for clinical diagnosis. This test is NABL accreditated but not FDA approved/CAP accreditated.
h. There is poor standardization between commercially available PCR tests, and results from different institutions should not be directly compared. Results are best monitored using a single institution.
i. All precautions were taken to ensure the accuracy of test results. Although molecular testing is highly accurate, rarely false-positive and false-negative diagnostic errors may occur.
j. False negative results caused by improper annealing of the PCR primers due to patient specific sequence mutations or alternative fusion transcript splice forms cannot be completely ruled out.
k. Linearity for BCR-ABL1 IS is till 10%.
l. All laboratory tests are associated with an error rate of ~1%. These could be due to sample mismatch, inappropriate labelling, processing or technological limitations. Please correlate with clinical features and other investigations for final conclusion and send a repeat sample for analysis if necessary.

REFERENCES:
1. Hughes TP, Kaeda J, Brandford S, Rudzki Z, Hochhaus A, Hansley ML et al. Frequency of major molecular responses to imatinib or interferonplus ctarabine in newly diagnosed chronic myeloid leukemia. N Engl J Med 2003;349:1423-32.
2. Foroni L, Wilson G, Gerrard G, Mason J, Grimwade D, White HE, de Castro DG, Austin S, et al. Guidelines for the measurement of BCR-ABL1 transcript in chronic myeloid leukemia. Br J Haematol 2011;153(2):179-90.
3. Baccarani M, Castagnetti F, Gugliotta G, Rosti G. A review of the European LeukemiaNet recommendations for the management of CML. Ann Hematol Â 2015;94 Suppl. 2:S141-7.

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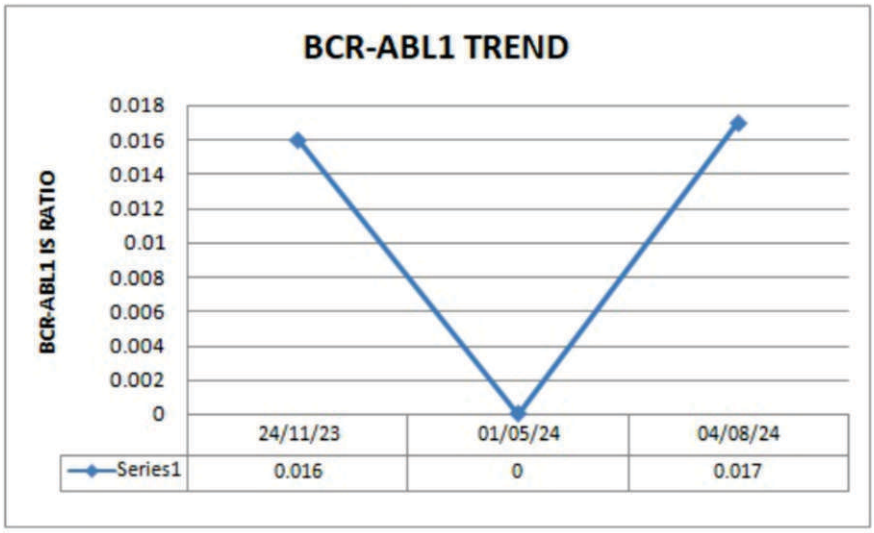

---------- End Of Report ----------

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