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MC-6043

To: Sehgal Path Lab Private Limited
103,Yashodhan Bldg 2, Four Bungalows,
Andheri West
Mumbai- 400053
Maharashtra
Report Of: Mr. RAGHAVENDRA NARAYAN SAVKAR

Sample ID	:	2400116255
Patient ID	:	1002430381
Collected on	:	06-06-2024
Received on	:	08-06-2024 10:44:00
Reported on	:	12-06-2024 05:46:15
Ref By	:	DR.KUNAL SEHGAL

MOLECULAR GENETICS REPORT

Patient Name	: **Mr. RAGHAVENDRA NARAYAN SAVKAR**	**Age**	:	**50 Years**
		Gender	:	**Male**
Physician Name	: **DR.KUNAL SEHGAL**	**Specimen**	:	**Ok**
Provisional Diagnosis	: **K/C/O CML**	**Status**		
		Disease Status	:	**Followup**
Specimen Type	: **Peripheral Blood (PB)**			
Test Requested	: **BCR-ABL1 RT-qPCR for p210 (IS)**			

Test : **BCR-ABL1 RT-qPCR for p210 (IS) Analysis.**

Result: Negative

BCR-ABL1 RT-qPCR for p210 (IS) Analysis:

BCR-ABL1 Type p210	ABL1 gene absolute copy number (aCN)	Normalized BCR-ABL1/ ABL1 ratio%	BCR-ABL1 International Scale (IS) %	Molecular Response
Not Detected	1,80,060 Copies	-	-	-

Conclusion: The specimen tested did not show the presence of BCR-ABL1 p210 transcript copies. As per NCCN 2020 guidelines of monitoring CML, this indicates complete molecular response or molecularly undetectable leukemia. Kindly co-relate with the clinical findings.

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Methodology:

Total RNA was extracted from the specimen, reverse transcribed and the common p210 fusion transcripts (b2a2 & b3a2) in chronic myeloid leukemia are measured with breakpoint probes using real-time polymerase chain reaction. ABL1 serves as an endogenous reference to monitor RNA quality and to report the percent relative ratio of BCR-ABL1 to ABL1. Levels of BCR-ABL1 are reported on a standardized International Scale (IS). On the IS, a major molecular response (MMR) represents a 3-log reduction in BCR-ABL and is defined as <=0.1 % IS. Deep molecular response-4 (DMR-4) represents a 4-log reduction from the IRIS baseline (<=0.01%IS); DMR-4.5 represents a 4.5-log reduction from IRIS baseline (<=0.0032%IS); DMR-5 represents a 5-log reduction from IRIS baseline (<=0.001%IS). Alternate/rare breakpoints are not detected/ quantitated in this assay. The limit of detection of this assay is 3 copies of the BCR-ABL1 transcript. The reproducibility of this assay is such that results within 0.5 log should be considered equivalent.

References:

1. Yoshida et al: Validation of a rapid one-step high sensitivity real-time quantitative PCR system for det ecting major BCR-ABL1 mRNA on an International Scale. Springer Plus 2016; 5: 569-575.
2. Cross N.C.P. et.al: Laboratory recommendations for scoring deep molecular responses following treat ment for chronic myeloid leukemia. Leukemia 2015; 29: 999-1003.
3. Baccarani et al: European Leukemia Net recommendations for the management of chronic myeloid le ukemia: Blood. 2013;122(6):872-884.
4. Branford et al: Desirable performance characteristics for BCR-ABL measurement on an international r eporting scale to allow consistent interpretation of individual patient response and comparison of res ponse rate between clinical trials. Blood 2008; 112: 3330-3338.
5. Jerald PR et al: Chronic Myeloid Leukemia, Version 1.2019, NCCN Clinical Practice Guidelines in Oncol ogy J Natl Compr Canc Netw. 2018;16(9):1108-1135.
6. NCCN Guidelines of monitoring Chronic Myeloid leukemia, 2020.

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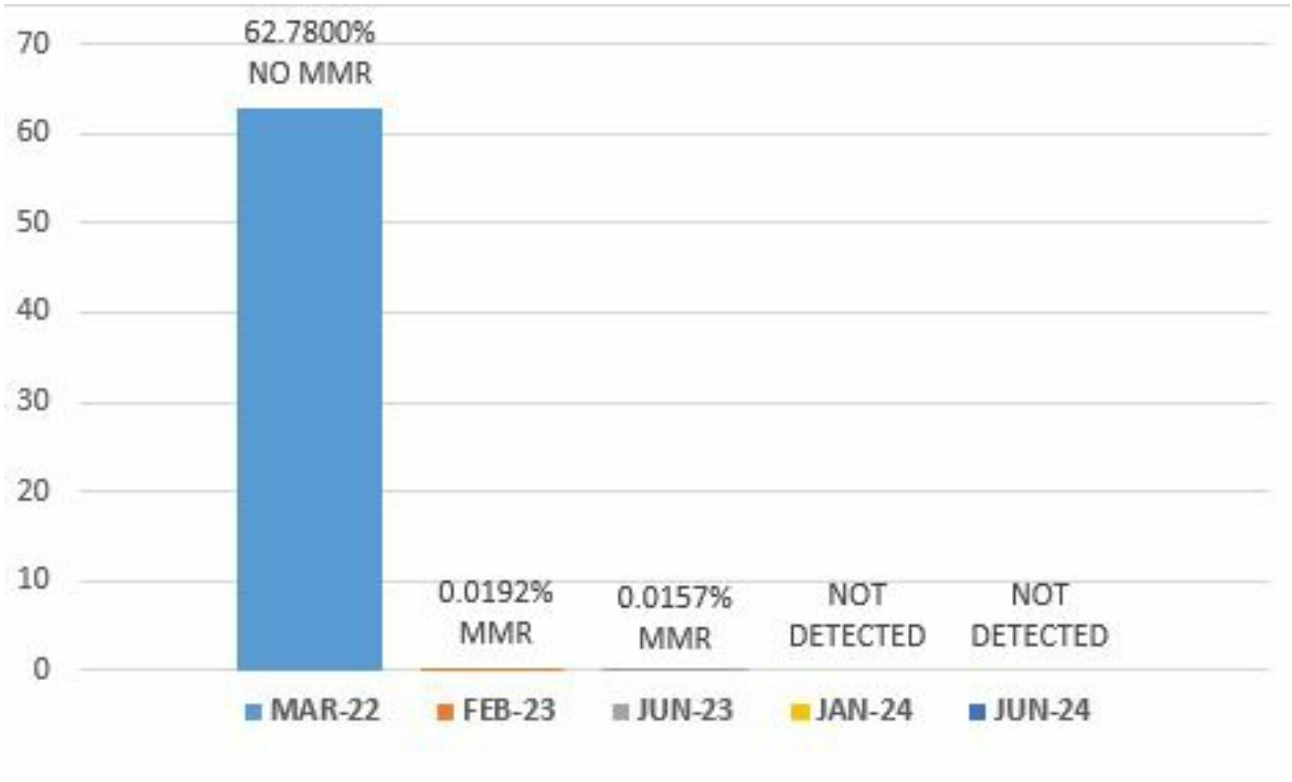
Mr. RAGHAVENDRA NARAYAN SAVKAR Sample ID: 2400116255



BCR-ABL1 RT-qPCR for p210 (IS)

Prepared By : **Priyanka Mandlik**
Verified By : **Dr.Darshana Mirgal**

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- End of Report -

Conditions of Reporting/Disclaimer:

- This report is based on the sample received in the Lilac Insights laboratory; the analysis is based on the assumption that samples received are representative of the patient mentioned on the test requisition form and the sample. When samples are received from various referral centers, it is presumed that patient demographics are verified at the point of sample collection.
- All samples for molecular studies must be collected in EDTA tubes (lavender cap). A sample where the test requisition requires RNA and subsequent cDNA conversion, must be maintained and transported at 4°C until it reaches Lilac Insights Pvt. Ltd. within 24 hours to prevent degradation of the RNA in the sample. FFPE tissue blocks often yield fragmented DNA of low concentrations which can impact result quality.
- Assays are performed in accordance with standard procedure on receipt. The reported results are dependent on individual assay methods, equipment used, method specificity, sensitivity and quality of specimen(s) received.
- Despite all the necessary precautions and stringency adopted whilst performing DNA tests, the currently available data indicates that the technical error rate associated with all types of DNA analysis, is approximately 2%.
- Although molecular testing is highly accurate, rarely false-positive & false-negative diagnostic errors may occur due to improper quality control during sample collection, cellular integrity of sample, selection of inappropriate specimen and/or presence of PCR inhibitors. PCR primer binding site polymorphisms or mutations might lead to allele dropout & cause false negative results.
- It is important that all clinicians or persons requesting DNA diagnostic tests are aware of these data before acting upon these results. As with all diagnostic tests, the laboratory report must be interpreted in conjunction with the presenting clinical profile of the patient and evaluation of all reports.
- In sequencing based tests sometimes variants of unknown significance (VUCS) are detected that have either not been reported before, and/or whose effect cannot be determined based on the current knowledge standards and reporting guidelines. In such cases, we recommend periodic review of these variants to determine any change in classification based on new published research.
- Lilac Insights Pvt. Ltd. has policy to return the FFPE blocks within one month after final reporting with proper documentation of the dispatch of the block to customer from accession dept, Lilac. After dispatch, if there is no intimation from customer within two weeks, Lilac will not be responsible for the dispatched FFPE block.
- Soft copies of reports are sent to customer by office mail ID. Also, Hardcopies are sent to customer only on the address provided by client.

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