LABORATORY REPORT

Redcliffe labs

Patient Name	:	Bill Date	:
DOB/Age/Gender	:	Sample Collected	:
Patient ID / UHID	:	Sample Received	:
Referred By	:	Report Date	:
Sample Type	:	Barcode No	:
Client	:	Report Status	:

MOLECULAR DIAGNOSTICS REPORT

Philadelphia Chromosome (BCR/ABL Quantitative)

BCR/ABL - Philadelphia Chromosome (IS - International Scale) Quantitative

TestPrinciple	Real Time Polymerase Chain Reaction
Specimen type	EDTA P Blood
Result	P210 (B3A2, B2A2) Major transcript (M-BCR) was detected

ABL1 copy number	**255,184 Copies**
BCR/ABL1 copy number	**3,950 Copies**
Conversion Factor IS	**0.703**
BCR-ABL1 Ratio % (IS)	**1.088 %**

Result:
IS Ratio:
The hybrid transcript for BCR-ABL1 was quantitated using International Scale RQPCR assay. The ratio of BCR-ABL1/ABL1 transcript as represented in IS scale was detected to be **1.088 %.**

Genomic Breakpoint Detected:
P210 (B3A2, B2A2) Major transcript (M-BCR) was detected

Analytical Sensitivity: 0.0032%

INTERPRETIVE REPORT :
If positive, the quantitative level is reported as the normalized ratio of bcr/abl1 (p210) to endogenous abl1 mRNA with conversion to a percentage referenced to the international scale (IS), on which 0.1% BCR-ABL1; ABL1 is designated as a major molecular response (MMR) threshold.

LIMITATION OF ASSAY :
1. PCR is a highly sensitive technique; common reasons for paradoxical results are contamination during specimencollection, selection of inappropriate specimen and inherent PCR inhibitors in the sample.
2. Laboratory tests are merely a tool to assist in the diagnosing process and should be clinically correlated by the Referring Physician.

TEST DETAILS :
1. The analytical sensitivity of this Test allows detection of 1 leukemic cell carrying the abnormal transcript in 100,000 normal cells
2. 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.

CLINICAL BACKGROUND :
1. In the vast majority of CML patients, and in up to 35% of Philadelphia chromosome-positive precursor B-ALL, the breakpoint on chromosome 22 is located between exons 12 and 16 (b1 to b5) of the BCR gene, in the major breakpoint cluster region (Mbcr).
2. The two most common M-bcr transcription products e13a2 (b2a2) and e14a2 (b3a2) gives rise to the BCR/ABL1 chimeric

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protein p210, a deregulated tyrosine kinase.
3. Copy number of BCR-ABL1 fusion transcripts (e13a2, e14a2, e1a2, or e19a2), ABL1 control gene is calculated based on the respective calibration curves

CLINICAL UTILITY :
1. The quantitative BCR-ABL RNA assay is intended to monitor the level of minimal residual disease in TKI-treated Philadelphia chromosome positive leukemia's (CML or ALL).
2. High or rising BCR-ABL RNA levels have been shown to increase the risk of leukemic relapse and drug-resistance mutations during TKI therapy.
3. The failure to achieve a "major molecular response", a 3- log drop in BCR-ABL RNA, defined as 0.1% on the BCR-ABL RNA PCR international scale (IS), is the consensus definition of a "sub-optimal" treatment that requires an alternative treatment approach.

COMMENTS :
1. It is recommended that RT-PCR test be performed at a frequency of every 3 months until major molecular response [MMR] is obtained following which the test can be done at a lesser frequency of once in every 6 months.
2. Lower limit of transcript detection is a factor of cellular integrity of the clinical sample.
3. Genetic variations have potential to alter PCR results and therefore the result should be interpreted in the light of clinical observations.

NOTE :
1. All test outcomes are subject to the nature of the sample received by the Laboratory.
2. Test results are not valid for any medico legal purposes.

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Terms and Conditions of Reporting

1. The presented findings in the Reports are intended solely for informational and interpretational purposes by the referring physician or other qualified medical professionals possessing a comprehensive understanding of reporting units, reference ranges, and technological limitations. The laboratory shall not be held liable for any interpretation or misinterpretation of the results, nor for any consequential or incidental damages arising from such interpretation.

2. It is to be presumed that the tests performed pertain to the specimen/sample attributed to the Customer's name or identification. It is presumed that the verification particulars have been cleared out by the customer or his/her representation at the point of generation of said specimen / sample. It is hereby clarified that the reports furnished are restricted solely to the given specimen only.

3. It is to be noted that variations in results may occur between different laboratories and over time, even for the same parameter for the same Customer. The assays are performed and conducted in accordance with standard procedures, and the reported outcomes are contingent on the specific individual assay methods and equipment(s) used, as well as the quality of the received specimen.

4. This report shall not be deemed valid or admissible for any medico-legal purposes.

5. The Customers assume full responsibility for apprising the Company of any factors that may impact the test finding. These factors, among others, includes dietary intake, alcohol, or medication / drug(s) consumption, or fasting. This list of factors is only representative and not exhaustive.