

Case ID

Patient Name

RAJENDRA PAL 10046174

102220377385

Age/Sex

39 Year /Male Noida, Uttar Pradesh, India

Hospital Location

Hospital Name

JITM Skills Private Limited, Noida

Physician Name

24/12/2022 18:35 Hrs

Dr. Self

Date & Time of Accessioning

Date & Time of Reporting

28/12/2022 13:43 Hrs

TEST NAME

BCR-ABL1 Quantitative International Scale [IS]

SPECIMEN INFORMATION

Peripheral Blood Collected on 24/12/2022 at 00:00 Hrs

CLINICAL HISTORY

NOT PROVIDED.

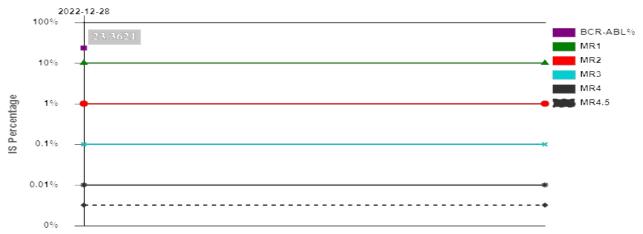
METHODOLOGY

Real Time Polymerase Chain Reaction (RT PCR)

TEST RESULT

P210 (b3a2, b2a2) major transcript	Detected
P190 (e1a2) minor transcript	Not detected
P230 (c3a2) micro transcript	Not detected
Observed copies of ABL1	183666
Observed copies of BCR-ABL1	67044
BCR-ABL1/ABL1 ratio [%]	36.50327681
Conversion Factor for IS	0.64
BCR-ABL1 IS [%]	23.3621

Patient IS% Historical Results



White blood cell(WBC) count = $106300.00/\mu$ l; Platelet count = $194000.00/\mu$ l; Hemoglobin = 11.60 g/dL





Dr. Shiyani Sharma DCP. D

Dr. Shivani Sharma, DCP, DNB Reg. No. 1906







Patient Name

Case ID

Age/Sex

RAJENDRA PAL 10046174

i delette i valiti

39 Year /Male

102220377385

Hospital Location Noida, Uttar Pradesh, India

Hospital Name JITM Skills Private Limited, Noida

Physician Name Dr. Self

Date & Time of Accessioning 24/12/2022 18:35 Hrs

Date & Time of Reporting 28/12/2022 13:43 Hrs



COMMENTS

1. The hybrid transcript of BCR-ABL1 was quantitated using Real-Time PCR assay. Signals for BCR-ABL1 P210 were detected in leukocytes of the specimen. Follow-up is recommended, if clinically indicated.

TEST INFORMATION

Background

1. Chronic myeloid leukaemia (CML), is characterized by the translocation between chromosomes 9 (9q34.1) and 22 (22q11.2). The t(9;22)(q34.1;q11.2) is detected cytogenetically in more than 91-96% of adult CML patients; in 5% of pediatric ALL-B CALLA positive; and 15-30% of adult ALL-B CALLA positive patients. At the molecular level, breaks in the BCR, and ABL1 genes result in the formation of fusion mRNA transcripts.

Assay Description, and Methodology

- 1. This assay quantifies the Major (p210), Minor (p190), and Micro (p230) transcripts. Its internal reference gene is ABL1. It is in accordance with EAC Guidelines, and uses an inhouse approved kit with high sensitivity (>MR4.5). Its IS conversion factor is established in accordance with the guidelines of Europe Against Cancer (EAC), and has been calibrated using WHO International Standards for CML.
- 2. Total cellular RNA is extracted via silica-membrane-based purification from whole blood or bone marrow collected in EDTA. The assay is an RT-qPCR that uses oligonucleotide hydrolysis principle.
- 3. Molecular Response (MR) is measured using % BCR-ABL ratio. The formula used is: % BCR-ABL1 = [No. of copies of BCR-ABL1 transcripts/No. of copies of control gene transcripts] x 100.
- 4. For the P210 transcript, this ratio is further normalized to the international scale (IS) and reported as BCR-ABL1/ABL1 % (IS). The formula used is: % BCR-ABLIS = [Sum of BCR-ABL1 copy number/Sum of ABL1 copy number* x CF x 100. Where *denotes minimum of 10,000 copies.
- 5. Molecular response is thus expressed and reported as BCR-ABL% on a log scale relative to the standard baseline (100% IS), where 10%, 1%, 0.1%, and 0.0032% correspond to a decrease of 1, 2, 3, and 4.5 logs, respectively, below the standard baseline, i.e. 100% BCR-ABL^{IS}.

Disclaimer: The in house assay is designed to perform the reactions at the specified analytical sensitivity given that the template RNA is not heavily fragmented, and does not contain materials that could inhibit the amplification reaction.

Recommendations: Real Time PCR is generally recommended until stable MMR is archieved followed by 3-to-6 month testing thereafter. BCR-ABL1 KD mutation testing is recommended both by the ELN and by the NCCN in CML patients who do not achieve an optimal response to TKI therapy.

REFERENCES

- Druker BJ, et al. IRIS Investigators. Five-year follow-up of patients receiving imatinib for chronic myeloid leukemia. N Engl J Med. 2006 Dec 7;355(23):2408-17.
- Branford S et al. Rationale for the recommendations for harmonizing current methodology for detecting BCR-ABL transcripts in patients with chronic myeloid leukaemia. Leukemia. 2006 Nov;20(11):1925-30.
- Baccarani M etal., European LeukemiaNet. Evolving concepts in the management of chronic myeloid leukemia: recommendations from an expert panel on behalf of the European LeukemiaNet. Blood. 2006 Sep 15;108(6):1809-20.
- Beillard E et al. Evaluation of candidate control genes for diagnosis and residual disease detection in leukemic patients using 'real-time' quantitative reverse-transcriptase polymerase chain reaction (RQ-PCR) a Europe against cancer program. Leukemia. 2003 Dec;17(12):2474-86.





Dr. Shivani Sharma, DCP, DNB

Reg. No. 1906

Dr. Rahul Katara, Ph.D.

CORE DIAGNOSTICS™



Patient Name

Hospital Location

Case ID

Age/Sex

RAJENDRA PAL 10046174

102220377385

39 Year /Male

TO SETVE TO

Noida, Uttar Pradesh, India

Hospital Name JITM Skills Private Limited, Noida

Physician Name Dr. Self

Date & Time of Accessioning 24/12/2022 18:35 Hrs

Date & Time of Reporting 28/12/2022 13:43 Hrs

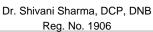
Report L

• Cross NC et al. Laboratory recommendations for scoring deep molecular responses following treatment for chronic myeloid leukemia. Leukemia. 2015 May;29(5):999-1003.











Dr. Rahul Katara, Ph.D.



Question?

Contact us at +91 124 4615 615

Toll Free Helpline +91 8882899999

CONDITIONS OF REPORTING

- 1. The tests are carried out in the lab with the presumption that the specimen belongs to the patient named or identified in the bill/test request form.
- 2. The test results relate specifically to the sample received in the lab and are presumed to have been generated and transported per specific instructions given by the physicians/laboratory.
- 3. The reported results are for information and are subject to confirmation and interpretation by the referring doctor.
- 4. Some tests are referred to other laboratories to provide a wider test menu to the customer.
- 5. Core Diagnostics Pvt. Ltd. shall in no event be liable for accidental damage, loss, or destruction of specimen, which is not attributable to any direct and mala fide act or omission of Core Diagnostics Pvt. Ltd. or its employees. Liability of Core Diagnostics Pvt. Ltd. for deficiency of services, or other errors and omissions shall be limited to fee paid by the patient for the relevant laboratory services.

This report is the property of CORE Diagnostics. The information contained in this report is strictly confidential and is only for the use of those authorized. If you have received this report by mistake, please contact CORE Diagnostics

CORE Diagnostics (Central Reference Lab) - Gurugram

406, Udyog Vihar, Phase III, Gurgaon-122016

CORE Diagnostics Lab - New Delhi

C-13, Green Park Extension, New Delhi-110016

CORE Diagnostics Lab - Lucknow

J.S. Tower, Plot No. K-702, Sector-K, Ashiyana, Near Raj Luxmi Sweets, Lucknow-226012 **CORE Diagnostics Lab - Bangalore**

1st Floor, KMK Tower, 142 KH Road, Bangalore-560027

CORE Diagnostics Lab - Bhubaneswar

Plot No. 249, Near Police Academy, AIIMS Nagar, Patrapada, Bhubaneswar-751019