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# Dean Medical Laboratory Report

## DIAN Medical Laboratory Test Report

Quantitative detection of BCR:: ABL1 (p210) fusion gene-(PCR-fluorescent probe method)

nspection unit: Shanghai Songjiang District Central Hospital

Dean Code: 990129374505

Name: YindiMiao
Gender: Female
Age: 79 years old

Type of Visit: Inpatient
Contact Number:
Submitting Doctor: Ruifeng Zhu

Department / Bed Number: Hepatology Ward / 5306
Outpatient / Inpatient Number: 71004266222
Clinical Diagnosis: Infectious fever, gallstones, Grade 1 hypertension (high)

Customer Code: 71004266222
Sample type: EDTA anticoagulated bone marrow
Sample Status: Normal appearance

| Item Name | Result | Unit | Reference Range |
|---|---|---|---|
| BCR::ABL1 p210 fusion gene | negative | | negative |
| BCR::ABL1 p210/ABL(IS) | 0.0000 | % | - |
| BCR::ABL1 p210/ABL | 0.0000 | % | - |
| BCR::ABL1 p210 | Below the detection limit | Copy | Below the detection limit |
| ABL internal reference gene | 2.07×10^5 | Copy | - |
| MR | >=4.00 | | |

ıg methods and equipment

Real-time quantitative PCR / ABI 7500

Explain and recomm

1. This project can detect BCR:: ABL1 fusion gene, which is used to assist clinical diagnosis and treatment:

The BCR::ABL1 fusion gene, formed by the t(9;22) translocation, is the most important molecular marker for chronic myeloid leukemia (CML) and a decisive factor in the disease. The BCR::ABL1 fusion gene is also expressed in a subset of adult acute lymphoblastic leukemia (20%-30%), childhood acute lymphoblastic leukemia (2%-10%), and acute myeloid leukemia patients.

BCR::ABL1 has three main fusion modes:

（1） p210 fusion protein: transcribed from b3a2 or b2a2, is the root cause of most chronic phase CML phenotypic abnormalities;

（2） p190 fusion protein: translated from a hybrid mRNA of the e1a2 linker resulting from a break in the BCR;

（3） p230 fusion protein: an e19a2 fusion produced downstream of the M-bcr region from the BCR breakpoint.

2. This project can detect the level of minimal residual lesions (MRD) in patients, evaluate the therapeutic effect of TKI drugs, and guide the use of drugs:

For patients with CML, the NCCN guidelines recommend the following:

（1） Three months after the start of treatment, if BCR::ABL1/ABL is ≤10%, continue with the same dose of medication. BCR::ABL1 transcriptional levels should be tested every three months thereafter;

（2） After achieving complete cytogenetic remission, follow-up examinations should be performed every 3 months, and after 2 years, examinations can be performed every 3-6 months;

（3） When BCR::ABL1 transcriptional levels increase (by 1 Log), but still reach the main molecular remission criteria, a follow-up test should be performed within 1-3 months;

（4） When the BCR::ABL1 transcriptional level test results show the following, it is recommended to perform ABL kinase domain mutation testing to investigate the cause of clinical TKI resistance: ① Chronic phase: Patients with poor initial response to TKI treatment (failure to achieve PCyR or BCR::ABL1/ABL>10% at 3-6 months; failure to achieve CCyR at 12 and 18 months); treatment failure.
(Hematological or cytogenetic relapse); BCR::ABL1 transcription level increases by 1 Log and MMR is lost. ② When the disease progresses to the accelerated or blast crisis phase.

For ALL patients, MRD testing is recommended as follo\

（1） Performed after the first induction chemotherapy to assess efficacy;

（2） Other testing time points can be determined as appropriate based on the treatment plan and clinical situation;

（3） It is recommended to have a follow-up examination every 3-6 months during maintenance treatment.

*This result is only responsible for the sample provided by this barcode. If you have any questions, please raise them within one week of the report's release.



Laboratory personnel: Yao Li
Reviewer: Xu Yang
Laboratory: Hangzhou Dian

Special seal for inspection

Sampling time: 2025-11-14 10:41
Receiving time: 2025-11-14 19:31
Reporting time: 2025-11-17 10:51

Address: Building 1, No. 329, Jinpeng Street, Sandun Town, Xihu District, Hangzhou
Tel: 4007118000

Receiving unit: Shanghai Dian Medical Laboratory

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## 备注

（1） Treatment efficacy and MRD monitoring reports are only for follow-up patients.

（2） Molecular biological remission is determined by BCR::ABL1 transcriptional level: BCR::ABL1/ABL≤0.1% (IS) or a decrease in transcriptional level ≥3 Log [decrease in transcriptional level
(Log) = -Log(BCR::ABL1 transcriptional level/standard baseline level)].

（3） The standard baseline is based on NCCN guidelines: In international standards, the standard baseline (median BCR::ABL1 mRNA transcript count at diagnosis in 30 CML patients in the IRIS study) is 100%. MMR refers to a decrease of 3 Logs from baseline in BCR::ABL1 transcript count to 0.1%. A decrease of 2 Logs and 1 Log from baseline is generally associated with CCyR and MCyR.
Closed. CMR is defined as the inability to detect BCR::ABL1 transcripts by Q-PCR after a decrease of 4.5 Logs or more from baseline.

（4） This assay uses the WHO BCR::ABL1 p210 standard to obtain a conversion factor (CF) value of 0.76, used for BCR::ABL1 (IS) conversion.

（5） CF is only valid when BCR::ABL1 (IS) ≤ 10%. When this value is > 10%, it only indicates that BCR::ABL1 (IS) > 10%, and the value is only for reference. The actual BCR::ABL1 level may be higher than this value.

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（6） The ABL internal reference gene is used to assess whether the white blood cell count of the sample meets the detection requirements. A negative result can be reported only when the count is ≥ 10; the detection limit for the target fusion gene is 10 copies.

## References

[1] Haguet H, Douxfils J, Mullier F, et al.Expert Opin Drug Saf. 2017;16(1):5-12.
[2] Ofran Y, Izraeli S. Blood Rev. 2017 Mar;31(2):11-16.
[3] NCCN Guidelines Version 1.2018. Chronic Myeloid Leukemia.

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