Dean Medical Laboratory Report

DIAN Medical Laboratory Test Report

Quantitative detection of BCR::ABL1 (p230) 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 p230 fusion gene	negative		negative
BCR::ABL1 p230/ABL	0.000	%	
BCR::ABL1 p230	Below the detection limit	Copy	Below the detection limit
ABL internal reference gene	2.07×10^5	Copy	-

ıg methods and equipment

Real-time quantitative PCR / ABI 7500

Explain and recomm

I. This project can detect BCR:: ABL1 (p230) fusion gene for auxiliary clinical diagnosis and treatment:

The BCR::ABL1 fusion gene is present in more than 95% of chronic myeloid leukemia (CML) patients and is the most important molecular marker of CML, a decisive factor in the disease. The BCR::ABL1 fusion gene is also expressed in some 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, it is the root cause of most chronic phase CML phenotypic abnormalities;

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

（3） p230 fusion protein: e19a2 fusion generated 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 starting 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 meet the criteria for major molecular remission, 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: Poor initial TKI treatment response (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 transcriptional levels increase by 1 Log and loss of MMR.

For ALL patients, MRD testing recommendations are as follows:

② When the disease progresses to the accelerated or blast crisis phase.

（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 retest every 3-6 months during maintenance treatment.

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

Sample 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 transcriptional level decrease ≥3Log[transcriptional level decrease (Log)=-Log(BCR::ABL1 transcriptional level/standard baseline level)].

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

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（4） ABL internal reference gene is used to assess whether the white blood cell count of the specimen meets the detection requirement. A negative result is required for reporting; the detection limit of the target fusion gene is 100 copies.
The lower limit for the comparison ratio (transcription level) report is 0.01%.

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.

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

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