

Dean Medical Laboratory Report

DIAN Medical Laboratory Test Report

Quantitative detection of BCR:: ABL1 (p190) fusion gene-(PCR-fluorescent probe method)

Inspection unit: Shanghai Songjiang District Central Hospital

Dean Code: 990129374505

Name: Yindi Miao	Type of Visit: Inpatient	Department / Bed Number: Hepatology Ward / 5306	Customer Code: 71004266222
Gender: Female		Outpatient / Inpatient Number: 71004266222	Sample type: EDTA anticoagulated bone marrow
Age: 79 years old	Submitting Doctor: Ruifeng Zhu	Clinical Diagnosis: Infectious fever, gallstones, Grade 1 hypertension (high)	Sample Status: Normal appearance

Item Name	Result	unit	Reference Range
BCR:: ABL1 p190	Below detection limit	Copy	Below detection limit
BCR:: ABL1 p190/ABL	0.000	%	
BCR:: ABL1 p190 fusion gene	negative		negative
ABL internal reference gene	2.07×10^5	Copy	

 Testing methods and equipment

Real-time quantitative PCR / ABI 7500

 Explain and recommend

1. This project can detect BCR:: ABL1 (p190) fusion gene, which is used to assist 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 the breakpoint;
- (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 $\leq 10\%$, 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 conducted every 3 months, and examinations can be conducted every 3-6 months after 2 years;
- (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 MMR is lost. ② When the disease progresses to the accelerated or blast crisis phase.

For ALL patients, MRD testing is recommended as follows:

- (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.

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

Address: Building 1, No. 329, Jimpeng Street, Sandun Town, Xihu District, Hangzhou

Sample receiving unit: Shanghai Dian Medical Laboratory



Tel: 4007118000



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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: $BCR::ABL1/ABL \leq 0.1\%$ (IS) or a decrease in transcriptional level $\geq 3\text{Log}[\text{decrease in transcriptional level} (\text{Log}) = -\text{Log}(BCR::ABL1 \text{ transcriptional level}/\text{standard baseline level})]$.
- (3) Standard baseline is based on NCCN guidelines: In international standards, the standard baseline (median value of BCR::ABL1 mRNA transcripts at diagnosis in 30 CML patients in the IRIS study) is 100%. MMR refers to a decrease of 3 Logs in BCR::ABL1 transcripts 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 transcripts from baseline that makes BCR::ABL1 transcripts undetectable by Q-PCR.
- (4) The ABL internal reference gene is used to assess whether the white blood cell count in the sample meets the detection requirements; a negative result can be reported only when it is ≥ 10 ; the detection limit for the target fusion gene is 10 copies.
The lower limit for the relative proportion (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.

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