

检验报告
Certificate of Analysis

No. COA20260423046

产品名称 Product Name	血细胞分析仪用质控物(阻抗法) Hematology Control	REF	N/A
批号 Lot No.	B0526L	型号 Model of the Reagent	BC-3D
物料编码 Material Code	105-003208-00	包装规格 Package Size	低值:3 mL×6
生产日期 Manufacture Date	2026-04-08	有效期 Expiry date	2026-08-05
标准依据 Standard basis	产品检验规范 Specification for Product Inspection		

检测项目 Subjects	接受标准 Accept criteria	检测结果 Results	结果判定 Conclusion
1、外观性状 Appearance			
外观 Appearance	应作为一种足够均匀的类血液物质，红色或暗红色液体，不得有凝块。 It should be a sufficiently homogeneous blood-like substance, red or dark red liquid, without any clots.	符合标准/Qualified	符合/Pass
2、装量 Volume			
装量-低值 Volume -L	≥3ml	3 mL	符合/Pass
3、性能 Performance			
参考值表-低值 Value sheet-L	(1) 国内发货的产品必须具备该批号产品的参考值表。 (2) 国际发货产品，如订单上有明确要求不需要参考值，此检验项目不涉及。 (1) Every batch of domestically shipped products must have a reference value table. (2) For the internationallly shipped products, if there is a clear requirement on the order that no reference value is required, this inspection item is not applicable.	符合标准/Qualified	符合/Pass
	BC-3600	BC-3600	
瓶内均匀性-低值 Uniformity in bottle-L	Gran%≤3.0(SD)	Gran%:1.1	符合/Pass

深圳迈瑞生物医疗电子股份有限公司
SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO.,LTD.
地址：深圳市南山区高新技术产业园科技南十二路迈瑞大厦 邮编：518057 电话：0755-8188 8998 传真：0755-26582680
Adress: Mindray Building, Keji 12th Road South, High-Tech Industrial Park,Nanshan, Shenzhen, 518057, P.R. China
Tel: +86 755 8188 8998 Fax: +86 755 26582680 Website: www.mindray.com



HGB≤3.0% (CV%)	HGB:0.88%
Lymph%≤1.5 (SD)	Lymph:1.2
MCV≤0.5% (CV%)	MCV:0.27%
Mid%≤1.5 (SD)	Mid:0.7
MPV≤5.0% (CV%)	MPV:2.09%
PLT≤8.0% (CV%)	PLT:4.67%
RBC≤3.0% (CV%)	RBC:0.88%
WBC≤5.0% (CV%)	WBC:3.26%

生物安全性-低值 Biosafety-L	HBsAg、HIV抗体、HCV抗体、TP抗体检测结果应 为阴性。		
	HBsAg , HIV antibody, HCV antibody, and TP antibody testing results of the calibrator should be negative.	阴性/negative	符合/Pass
	BC-3600	BC-3600	
赋值准确性-低值 Accuracy of assignment-L	Gran#:±0.2	Gran#:0.0	符合/Pass



Gran%: ±9.0	Gran%:0.5
HCT %: ±2.0	HCT:-1.7
HGB g/L: ±5	HGB:-2
Lymph#: ±0.3	Lymph#:0.0
Lymph%: ±12.0	Lymph%:-0.7
MCH Pg: ±2.5	MCH:0.7
MCHC g/L: ±30	MCHC:23 g/L
MCV fL: ±5.0	MCV:-3.1
Mid#: ±0.2	Mid#:0.0
Mid%: ±9.0	Mid%:0.2
MPV fL: ±3.0	MPV:0.4



PCT: ±0.05	PCT: 0.00
PDW : ±3.0	PDW: 0.0
P-LCC* : ±15	P-LCC*: 1
P-LCR*: ±8.0	P-LCR*: 3.1
PLT×10 ⁹ /L: ±30	PLT: -3
RBC×10 ¹² /L: ±0.20	RBC: -0.13
RDW-CV: ±3.0	RDW-CV (RDW): 1.5
RDW-SD : ±10.0	RDW-SD: 3.7
WBC×10 ⁹ /L: ±0.5	WBC: 0.0

结论
Summary

合格/PASS

备注
Remarks

检验：
Analysis

洪坤Hong Kun

洪坤 Hong Kun

批准（检验工程师）：
Approved by(Quality Engineer)

郭小夕Guo Xiaoxi

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日期：
Date

2026-04-23

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