

检验报告
Certificate of Analysis

No. COA20260423052

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.	B0526H	型号 Model of the Reagent	BC-3D
物料编码 Material Code	105-003206-00	包装规格 Package Size	高值: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-高值 Volume-H	≥3ml	3 mL	符合/Pass
3、性能 Performance			
参考值表-高值 Value sheet-H	(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
瓶内均匀性-高值 Uniformity in bottle-H	BC-3600 Gran%≤3.0 (SD)	BC-3600 Gran%:0.4	符合/Pass



HGB≤1.5% (CV%)	HGB:0.66%
Lymph%≤3.0 (SD)	Lymph:0.2
MCV≤0.5% (CV%)	MCV:0.20%
Mid%≤1.5 (SD)	Mid:0.3
MPV≤4.0% (CV%)	MPV:1.00%
PLT≤4.0% (CV%)	PLT:1.01%
RBC≤1.5% (CV%)	RBC:0.64%
WBC≤3.0% (CV%)	WBC:0.88%

生物安全性-高值 Biosafety-H	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
	BC-3600	符合/Pass
赋值准确性-高值 Accuracy of assignment-H	Gran#:±2.0	
		Gran#:0.7
		符合/Pass



Gran%: ±9.0	Gran%:0.2
HCT %: ±4.0	HCT:-3.1
HGB g/L: ±10	HGB:2
Lymph#: ±1.8	Lymph#:0.9
Lymph%: ±8.0	Lymph%:-0.3
MCH Pg: ±2.5	MCH:0.9
MCHC g/L: ±30	MCHC:24
MCV fL: ±5.0	MCV:-3.7
Mid#: ±1.3	Mid#:0.1
Mid%: ±5.5	Mid%:0.1
MPV fL: ±3.0	MPV:0.0



PCT: ±0.20	PCT: -0.01
PDW : ±3.0	PDW: -0.2
P-LCC* : ±35	P-LCC*: -8
P-LCR*: ±8.0	P-LCR*: -1.0
PLT×10 ⁹ /L: ±70	PLT: -10
RBC×10 ¹² /L: ±0.35	RBC: -0.11
RDW-CV: ±3.0	RDW-CV (RDW) : 1.3
RDW-SD : ±12.0	RDW-SD: 2.4
WBC×10 ⁹ /L: ±2.5	WBC: 0.8

结论
Summary

合格/PASS

备注
Remarks

检验：
Analysis

洪坤Hong Kun

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

郭小夕Guo Xiaoxi

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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



日期：
Date

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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

Address: 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

