

检验报告  
Certificate of Analysis

No. COA20260109031

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.	B0226	型号 Model of the Reagent	BC-3D
物料编码 Material Code	105-003228-00	包装规格 Package Size	H: 3 mL×2 N: 3 mL×2 L: 3 mL×2
生产日期 Manufacture Date	2026-01-06	有效期 Expiry date	2026-05-05
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	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。		
外观 Appearance	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-中值 Volume -N	$\geq 3\text{ml}$	3 mL	符合/Pass
装量-低值 Volume -L	$\geq 3\text{ml}$	3 mL	符合/Pass
装量-高值 Volume -H	$\geq 3\text{ml}$	3 mL	符合/Pass
3、性能 Performance			
瓶内均匀性-中值 Uniformity in bottle-N	$\text{Gran}\% \leq 3.0(\text{SD})$	BC-3600  Gran%:0.5	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.

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HGB≤1.5% (CV%)	HGB:0.49%
Lymph%≤1.5 (SD)	Lymph%:0.5
MCV≤0.5% (CV%)	MCV:0.26%
Mid%≤1.5 (SD)	Mid%:0.2
MPV≤4.0% (CV%)	MPV:1.18%
PLT≤4.0% (CV%)	PLT:2.61%
RBC≤1.5% (CV%)	RBC:0.98%
WBC≤2.0% (CV%)	WBC:1.37%
BC-3600	BC-3600
Gran%≤3.0 (SD)	Gran%:1.0

瓶内均匀性-低值  
Uniformity in  
bottle-L

HGB≤3.0% (CV%)	HGB:1.11%
Lymph%≤1.5 (SD)	Lymph%:1.2

符合/Pass

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Gran%: ±10.0	Gran%:0.3
HCT %: ±3.0	HCT:-2.4
HGB g/L: ±8	HGB:0
Lymph#: ±0.7	Lymph#:0.
Lymph%: ±8.0	Lymph%:-0
MCH Pg: ±2.5	MCH:0.9
MCHC g/L: ±30	MCHC:20
MCV fL: ±5.0	MCV:-2.1
Mid#: ±0.6	Mid#:0.0
Mid%: ±7.0	Mid%:0.2
MPV fL: ±3.0	MPV:0.0

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PCT: ±0.10	PCT:-0.01
PDW : ±3.0	PDW:-0.1
P-LCC* : ±25	P-LCC*:-4
P-LCR*: ±8.0	P-LCR*:-0.1
PLT×10 <sup>9</sup> /L: ±55	PLT:-12
RBC×10 <sup>12</sup> /L: ±0.28	RBC:-0.17
RDW-CV: ±3.0	RDW-CV (RDW): 1.4
RDW-SD : ±10.0	RDW-SD: 1.1
WBC×10 <sup>9</sup> /L: ±1.0	WBC:-0.1
BC-3600	BC-3600

赋值准确性-低值  
Accuracy of  
assignment-L

Gran#: ±0.2

Gran#: 0.1

符合/Pass

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Gran%: ±9.0	Gran%: 0.8
HCT %: ±2.0	HCT: -1.0
HGB g/L: ±5	HGB: 1
Lymph#: ±0.3	Lymph#: -0.1
Lymph%: ±12.0	Lymph%: -1.4
MCH Pg: ±2.5	MCH: 1.2
MCHC g/L: ±30	MCHC: 24 g/L
MCV fL: ±5.0	MCV: -2.1
Mid#: ±0.2	Mid#: 0.0
Mid%: ±9.0	Mid%: 0.6
MPV fL: ±3.0	MPV: 0.2

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Gran%: ±9.0

Gran%:0.2

HCT %: ±4.0

HCT:-3.2

HGB g/L: ±10

HGB:0

Lymph#: ±1.8

Lymph#:0.0

Lymph%: ±8.0

Lymph%:-0.3

MCH Pg: ±2.5

MCH:0.6

MCHC g/L: ±30

MCHC:20

MCV fL: ±5.0

MCV:-3.3

Mid#: ±1.3

Mid#:0.0

Mid%: ±5.5

Mid%:0.1

MPV fL: ±3.0

MPV:0.2

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PCT: ±0.20	PCT: 0.01
PDW : ±3.0	PDW: 0.2
P-LCC* : ±35	P-LCC*: 9
P-LCR*: ±8.0	P-LCR*: 1.8
PLT × 10 <sup>9</sup> /L: ±70	PLT: -4
RBC × 10 <sup>12</sup> /L: ±0.35	RBC: -0.14
RDW-CV: ±3.0	RDW-CV (RDW): 1.3
RDW-SD : ±12.0	RDW-SD: 0.6
WBC × 10 <sup>9</sup> /L: ±2.5	WBC: 0.2

**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

*郭小夕 Guo Xiaoxi*

**日期:**  
**Date**

2026-01-12

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