

检验报告
Certificate of Analysis

No. COA20251015067

产品名称 Product Name	血细胞分析用溶血剂 M-20CFL LYSE	REF	N/A
批号 Lot No.	2025101451	型号 Model of the Reagent	M-20CFL
物料编码 Material Code	105-012726-00	包装规格 Package Size	100 mL×4
生产日期 Manufacture Date	2025-10-14	有效期 Expiry date	2027-10-13
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	应为澄清液体，不得有沉淀、颗粒或絮状物； Clear liquid, with no sediment, no particle, and no floccule.	符合标准/Qualified	符合/Pass
2、装量 Volume	装量(净含量) Volume (Net content) $\geq 100\text{mL}$	137 mL	符合/Pass
3、性能 Performance	pH值 pH Value 7.80 ± 0.20 (25°C $\pm 1^\circ\text{C}$)	样品1:7.79 (24.2°C); 样品2: 7.86 (24.3°C); 样品3:7.86 (24.3°C)	符合/Pass
	BC-3000Plus Gran%相对偏差在 $\pm 5\%$ 范围内 Relative Deviation $\pm 5\%$ range	BC-3000Plus Gran%:-0.56%	
准确性 Accuracy	HGB相对偏差在 $\pm 3.5\%$ 范围内 Relative Deviation in $\pm 3.5\%$ range	HGB:0.00%	符合/Pass

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Lymph%相对偏差在±8%范围内
Relative Deviation in ±8% range Lymph%: 2.86%

WBC相对偏差在±7.5%范围内
Relative Deviation in ±7.5% range WBC: -0.35%

吸收峰波长
Wavelength of the peak in a spectrum
吸收峰波长应在538±10nm范围内:
Wavelength of the peak in a spectrum:
样品1:536.00;样品2:536.00;样品3:536.00
符合/Pass
538±10nm

BC-3000Plus
a) 具备小细胞和大细胞两个细胞峰;
b) 35fL以内无干扰峰;
c) 淋巴细胞 (Lymph) 峰位置在25-65fL之间, 粒细胞 (Gran) 峰位置在150fL以上, 中间值细胞 (Mid) 峰位置在65fL-150fL之间;
a) There is a microcyte hump and a macrocyte hump;
b) The position of lymphocyte hump is between 25fL-65fL, the position of monocyte hump is above 150fL, and the position of mid-sized cell is between 65fL-150fL
BC-3000Plus
符合标准/Qualified
符合/Pass
WBC Histogram
No interference hump within 35fL;

BC-3000Plus BC-3000Plus

HGB≤1g/L HGB: 样品1:0.00;样品2:0.00;样品3:0.00

空白计数(空白值)
Background (Blank value)
符合/Pass

WBC≤0.3×10⁹/L WBC: 样品1:0.00;样品2:0.00;样品3:0.00

结论
Summary 合格/PASS

备注
Remarks

检验: 洪坤 Hong Kun *洪坤 Hong Kun* 批准(检验工程师): 韦晓露 Wei Xiaolu *韦晓露 Wei Xiaolu*
Analysis Approved by (Quality Engineer)
日期: 2025-10-15 日期: 2025-10-15
Date Date

