



# 校准物/质控物出厂检验报告

## Calibrator/Control Inspection Report

|                          |                     |                                                                                                                                                         |                         |                                                                            |                |
|--------------------------|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------------------------------------------------------------|----------------|
| 产品名称<br>Product Name     |                     | 血细胞分析仪用质控物（阻抗法）<br>Quality Control for Hematology Analyzer (Impedance Method)                                                                           |                         |                                                                            |                |
| 规格<br>Specification      |                     | 3mL                                                                                                                                                     |                         |                                                                            |                |
| 批号<br>Batch No.          |                     | 2505L                                                                                                                                                   | 有效期<br>Expiration Date  | 2025. 08. 26                                                               |                |
| 生产日期<br>Production Date  |                     | 2025. 05. 29                                                                                                                                            | 检验日期<br>Inspection Date | 2025. 06. 12                                                               |                |
| 检验项目<br>Inspection Items |                     | 检验标准<br>Inspection Standard                                                                                                                             |                         | 检验结果<br>Inspection Results                                                 | 判定<br>Judgment |
| 1                        | 外观<br>Appearance    | 足够均匀的血液类物质，不可有凝块。标签上有完整的批号、有效期，应清晰准确。<br>Calibration for uniform blood class material, Mark the batch number and self life of the labeled as a complete |                         | 符合<br>Meet with the requirement                                            | 合格<br>Pass     |
| 2                        | 装量<br>Net volume    | 装量负偏差不大于标示量的3%。<br>The load negative deviation less than 3%                                                                                             |                         | 符合<br>Meet with the requirement                                            | 合格<br>Pass     |
| 3                        | 瓶内均匀性<br>Uniformity | 瓶内均匀性（CV%）应满足：<br>solution uniformity (CV%)：<br>WBC≤3%<br>RBC≤2%<br>HGB≤2%<br>HCT≤2%<br>MCV≤1.0%<br>PLT≤10%                                             |                         | WBC: 2.9%<br>RBC: 0.9%<br>HGB: 1.0%<br>HCT: 1.0%<br>MCV: 0.4%<br>PLT: 8.3% | 合格<br>Pass     |
| 结论<br>Conclusion         |                     | 合格<br>Pass                                                                                                                                              |                         |                                                                            |                |
| 检验员<br>Inspector         |                     | 银少彤                                                                                                                                                     | 复核人<br>Reviewer         | 高曼姿                                                                        |                |
| 日期<br>Date               |                     | 2025. 06. 12                                                                                                                                            | 日期<br>Date              | 2025. 06. 12                                                               |                |

注：若无内容填写应用“/”。

Note: If there is no information, please fill with "/".

表格编号/Form Number: RT-RFM-Q8505

REV: A.2/ 保存期限: 10年/Storage Life: 10 years