



# 化学发光试剂出厂检验报告

## Chemiluminescence Reagent Inspection Report

产品名称 Product Name	25-羟基维生素D (25-OH VD) 测定试剂盒 (化学发光免疫分析法) 25-Hydroxy Vitamin D (25-OH VD) Reagent Kit (Chemiluminescent Immunoassay)		
规格 Specification	50T/盒 50Tests/Kit	产品型号 Product Model	/
批号 Batch No.	20250430	有效期 Expiration Date	2026.04.29
生产日期 Production Date	2025.04.30	检验日期 Inspection Date	2025.05.07
检验项目 Inspection Items	检验标准 Inspection Standard	检验结果 Inspection Results	判定 Judgment
1 外观 Appearance	①. 试剂M为棕褐色悬浊液, 久置后, 棕褐色磁珠沉于底部, 上清液为澄明液体; ②. 试剂R1为无色澄明液体; ③. 试剂R2为无色澄明液体; ④. 校准品和质控品为淡黄色澄明液体。 ①. The reagent M is a brown brown suspension, after a long time, the brown brown magnetic beads are deposited on the bottom, and the supernatant liquid should be clear liquid; ②. The reagent R1 a is colorless and clear liquid; ③. The reagent R2 a is colorless and clear liquid; ④. The calibration and the quality control product for yellowish clear liquid	符合  Meet with the requirement	合格  Pass
2 净含量 Net volume	液体试剂的净含量应不少于标示值 The net volume of liquid reagents should not be less than the indicated value.	符合 Meet with the requirement	合格 Pass
3 准确度 Accuracy	企业参考品相对偏差不得超过±10%; 质控品相对偏差不得超过±20% The relative deviation of enterprise reference standards should not exceed ±10%; number of quality control product relative deviation less than ±20%.	Q1: 1.30% Q2: -1.32% 准确性样本1 Accuracy1: 3.08% 准确性样本2 Accuracy2: 1.20%	合格  Pass
4 重复性 Repeatability	CV≤8%	低值 Low-level: 3.48% 高值 High-level: 3.48%	合格  Pass
5 线性范围 Linearity range	4-150 ng/mL内, $r \geq 0.990$ Within the range of 4-150 ng/mL, the correlation coefficient (r) should be $\geq 0.990$ .	结果 Result: r= 0.9979	合格  Pass
结论 Conclusion	合格 Pass		
检验员 Inspector	钟宗崇	复核人 Reviewer	高曼姿
日期 Date	2025.05.07	日期 Date	

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-Q8504

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

