



# 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	50测试/盒 50Tests/Kit	产品型号 Product Model	/	
批号 Batch No.	20250626	有效期 Expiration Date	2026.06.25	
生产日期 Production Date	2025.06.26	检验日期 Inspection Date	2025.07.02	
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, 上清液为澄清液体; ②. 试剂R1为无色澄清液体; ③. 试剂R2为无色澄清液体; ④. 校准品和质控品为淡黄色澄清液体。 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 合格 Meet with the requirement 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 合格 Meet with the requirement Pass
3	准确度 Accuracy	企业参考品相对偏差不超过±15%; 质控品相对偏差不超过±20% The relative deviation of enterprise reference standards should not exceed ±15%; number of quality control product relative deviation less than ±20%.		Q1: -2.01% Q2: -6.20% 准确性样本1 Accuracy1: -5.01% 准确性样本2 Accuracy2: -5.72% 合格 Pass
4	重复性 Repeatability	CV≤8%		低值 Low-level: 3.06% 高值 High-level: 1.33% 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: $r = 0.9977$ 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		2025.07.02	日期 Date	2025.07.02

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