

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.		20250423	有效期 Expiration Date	2026.04.22	
生产日期 Production Date		2025.04.23	检验日期 Inspection Date	2025.04.24	
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 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: 2.01% Q2: 1.24% 准确性样本1 Accuracy1: -6.94% 准确性样本2 Accuracy2: -4.66%	合格 Pass
4	重复性 Repeatability	CV≤8%		低值 Low-level: 7.25% 高值 High-level: 3.18%	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 ≥ 0.990 .		结果 Result: $r = 0.9942$	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		2025.04.24	日期 Date	2025.04.24	

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