



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%
4	重复性 Repeatability	CV≤8%	低值 Low-level:	3.48%
			高值 High-level:	3.48%
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=	0.9979 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	2025.05.07	

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