

化学发光试剂出厂检验报告



Chemiluminescence Reagent Inspection Report

产品名称 Product Name		总三碘甲状腺原氨酸 (TT3) 测定试剂盒 (化学发光免疫分析法) Total Triiodothyronine (TT3) Reagent Kit (Chemiluminescent Immunoassay)		
规格 Specification		50测试/盒 50Tests/Kit	产品型号 Product Model	/
批号 Batch No.		20250624	有效期 Expiration Date	2026.06.23
生产日期 Production Date		2025.06.24	检验日期 Inspection Date	2025.06.26
检验项目 Inspection Items		检验标准 Inspection Standard		检验结果 Inspection Results
1	外观	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为黄绿色澄清液体; ③. 试剂R2为无色澄清液体; ④. 校准品和质控品为无色澄清液体。		符合
	Appearance	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. Reagent R1 is yellow-green clear liquid; ③. Reagent R2 is a colorless clear liquid; ④. The calibration and the quality control product for colorless clear liquid.		Meet with the requirement
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
3	准确度 Accuracy	企业参考品相对偏差不超过 $\pm 10\%$; 质控品相对偏差不超过 $\pm 20\%$ The relative deviation of enterprise reference standards should not exceed $\pm 10\%$; number of quality control product relative deviation less than $\pm 20\%$.	Q1:	3.46%
			Q2:	-4.00%
			准确性样本1 Accuracy1:	2.22%
			准确性样本2 Accuracy2:	6.67%
4	重复性 Repeatability	CV $\leq 8\%$	低值 Low-level:	3.21%
			高值 High-level:	3.27%
5	线性范围 Linearity range	0.3~6.5 ng/mL内, $r \geq 0.9900$ Within the range of 0.3~6.5 ng/mL, the correlation coefficient (r) should be ≥ 0.99 .	结果 Result:	0.9989
结论 Conclusion		合格 Pass		
检验员 Inspector		钟宗崇	复核人 Reviewer	高曼姿
日期 Date		2025.06.26	日期 Date	2025.06.26

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