



检验报告

Certificate of Analysis

产品名称 Product Name		全段甲状旁腺素 (PTH) 测定试剂盒 (化学发光免疫分析法) Parathyroid Hormone (PTH) Reagent Kit (Chemiluminescent Immunoassay)		
产品型号 Product Model		/	包装规格 Package Size	50测试/盒 50Tests/Kit
批 号 Lot No.		20250806	有效期 Expiry Date	2026.08.05
生产日期 Manufacture Date		2025.08.06	检验日期 Inspection Date	2025.08.12
检验项目 Subjects		检验标准 Inspection Standards		检验结果 Results
1	外观 Appearance	①试剂M为棕(黄)褐色悬浊液,久置后,棕(黄)褐色磁珠沉于底部,上清液为澄清液体 The reagent M is a brown (yellow) brown suspension, after a long time, the brown (yellow) brown magnetic beads are deposited on the bottom, and the supernatant liquid should be clear liquid ②试剂R为无色或乳白色澄清液体 Reagent R is colorless or milky clear liquid ③校准品和质控品为无色或乳白色澄清液体 The calibration and quality control should be colorless or milky clear liquid		符合 Meet with the requirement
2	净含量 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±10% The relative deviation of enterprise reference standards should not exceed ±10%		准确性样本1 Accuracy 1 -5.74%
				准确性样本2 Accuracy 2 2.33%
4	重复性 Repeatability	CV≤8%		低值 Low-level 2.70%
				高值 High-level 1.58%
5	线性范围 Linearity range	1.2-4000 pg/mL内, r≥0.9900 Within the range of 1.2-4000 pg/mL, the correlation coefficient (r) should be ≥ 0.9900		0.9957
检验结论 Inspection Conclusion		合格 Pass		
报告人 Reporter		李庆琴	日期 Date	2025.08.12
批准(检验工程师) Approved by (Quality Engineer)		高曼姿	日期 Date	2025.08.12
备注 Remarks		若无内容填写应用“/”。 If there is no information, please fill with“/”.		

表格编号/Form Number: RT-RFM-Q8506

REV: A.0/ 保存期限: 10年/Storage Life: 10 years