检 验 报 告
Certificate of Analysis

No. COA20250222093

产品名称 Product Name	D-二聚体(D-Dimer)测定试剂盒(胶乳增强免疫透射比浊法) D-Dimer Kit (Particle-enhanced Immunoturbidimetric Assay Method)	**REF**	N/A
批号 Lot No.	045725003	**型号 Model of the Reagent**	N/A
物料编码 Material Code	105-004498-00	**包装规格 Package Size**	R1: 1×40 mL R2: 1×15 mL Calibrator: 6×0.5 mL
生产日期 Manufacture Date	N/A	**有效期 Expiry date**	2026-05-17
标准依据 Standard basis	产品检验规范 Specification for Product Inspection		

检测项目 Subjects	接受标准 Accept criteria	检测结果 Results	结果判定 Conclusion
1、外观性状 Appearance			
外包装检验 Outer packaging inspection	试剂外包装完整，标识清晰，密封良好，无破裂现象。试剂瓶液体无渗漏，标签完好清晰，是无标签脱落、污损现象，批号、效期信息完整。The reagent package is complete, clearly marked, well sealed, and free from cracking.	试剂外包装完整，标识清晰，密封良好，无破裂现象。试剂瓶液体无渗漏，标签完好清晰，是无标签脱落、污损现象，批号、效期信息完整。The reagent package is complete, clearly marked, well sealed, and free from cracking.	符合/Pass
外观物理性状 Appearance	校准品：冻干粉，复溶后为清澈透明液体，无沉淀、悬浮物和絮状物。Calibrator: dry powder, clear liquid without deposit, flocculate or suspended substance after redissolved R1：澄清透明的液体，无沉淀、悬浮物和絮状物；R2：白色混浊液体。R1, Clear liquid without deposit, flocculate or suspended substance; R2, white turbid liquid	Calibrator:校准品：冻干粉，复溶后为清澈透明液体，无沉淀、悬浮物和絮状物。Calibrator: dry powder, clear liquid without deposit, flocculate or suspended substance after redissolved R1/R2:R1：澄清透明的液体，无沉淀、悬浮物和絮状物；R2：白色混浊液体。R1, Clear liquid without deposit, flocculate or suspended substance; R2, white turbid liquid	符合/Pass
2、装量 Volume			
净含量 Volume	R2≥15mL	16.14 mL	符合/Pass

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	R1≥40mL	41.16 mL	

3、性能
Performance

准确度 Accuracy	测定质控血清，测定结果在靶值范围内。 靶值范围/target range: 1.52(1.07~1.97) μg/mL Testing results of Quality control should be within target range. 测定质控血清，测定结果在靶值范围内。 靶值范围/target range: 15.5(13.1~17.9) μg/mL Testing results of Quality control should be within target range.	Control(level 1) :1.39 μg/mL Control(level 2):14.75 μg/mL	符合/Pass
校准品均一性 Homogeneity of Calibrator	校准品的均一性 CV≤10.0%或SD≤0.07μg/mL。 Homogeneity of Calibrator CV≤10.0% or SD≤0.07μg/mL.	SD:0.04 CV:0.41%	符合/Pass
生物安全性 Biosafety	校准品的HBsAg、HIV抗体、HCV抗体、TP抗体检测应为阴性。 The test of hbsag, hiv antibody, hcv antibody and tp antibody of the calibration product should be negative.	阴性/negative	符合/Pass
空白吸光度 Blank Absorbance	试剂空白吸光度＜1.5A。 Reagent blank absorbance should be＜1.5A	1.48 A	符合/Pass
线性范围 Linearity Range	试剂盒在（0.5~48）μg/mL范围内，其回归系数r ≥0.9900。 样本浓度≤1.4μg/mL时，线性绝对偏差≤±0.14 μg/mL；样本浓度>1.4μg/mL时，线性相对偏差≤±10.0%。 In the range of 0.5~48 μg/mL the linear correlation coefficient r≥0.9900. The absolute deviation should be ≤±0.14 μg/mL(analyte concentrate ≤1.4 μg/mL)；the relative deviation should be ≤±10.0%(analyte concentrate >1.4 μg/mL)	相关系数R:0.9980;相对偏差/Relative deviation: Max:3.44%,Min:-3.55%	符合/Pass
重复性 Precision Within-run	批内变异系数 CV≤ 10.0%。 Within-run imprecision CV≤10.0%	SD:0.1;CV:0.6%	符合/Pass

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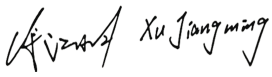
结论
Summary

合格/PASS

备注
Remarks

检验： **Analysis**	徐江明Xu Jiangming		**批准（检验工程师）：** **Approved by(Quality Engineer)**	黄小凤Huang Xiaofeng	
日期： **Date**	2025-02-22		**日期：** **Date**	2025-02-22	

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