

检验报告 Certificate of Analysis

No. COA20250511024

产品名称 尿/脑脊液总蛋白(TPUC)质控品 **Product Name** TPUC Control

N/A

105-009193-00

批号 060525005 Lot No.

物料编码 **Material Code**

生产日期 Manufacture

Date

标准依据 Standard basis **REF** N/A

型号

Model of the Reagent

Package Size

N/A

 $L:1\times1$ mL+H:1×1 mL

有效期

2026-09-30 **Expiry date**

产品检验规范 Specification for Product Inspection

			 结果判定
Subjects 1、外观性状 Appearance	Accept criteria	Results	Conclusion
包装检验 Package	试剂瓶应无泄漏; 盒贴、瓶贴、标签标识应完整、清晰。 The vial should be complete and leak-free ,the label should be complete and clear.	试剂瓶无泄漏; 盒贴、瓶贴、标签 标识完整、清晰。 The vial were complete and leak-free ,the label were complete and clear.	符合/Pass
参考值表 Reference value table	质控品应提供本批产品的参考值和参考范围。 Provide reference values and reference ranges for this batch of products.	质控品提供本批产品的参考值和参 考范围。 Provide reference values and reference ranges for this batch of products.	符合/Pass
颜色性状 Apparent properties 2、装量 Volume	澄清透明的液体,无沉淀、悬浮物和絮状物。 Clear and colorless liquid without precipitate, suspension and floccule	澄清透明的液体,无沉淀、悬浮物和絮状物。 Clear and colorless liquid without precipitate, suspension and floccule	符合/Pass
装量 Volume	Control(2 level)≥1mL	水平1: 1mL;水平2: 1mL	符合/Pass
3、性能 Performance			
参考值及参考范围 Reference and reference range	质控品检测值应在其参考范围内 靶值范围/ target range: 529(451~607)mg/L Testing results of Quality control should be within target range.	Control H:测试结果1: 527.46; 测试结果2: 520.26; 测试结果3: 519.83	符合/Pass

深圳迈瑞生物医疗电子股份有限公司

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. 地址: 深圳市南山区高新技术产业园区科技南十二路迈瑞大厦 邮编: 518057 电话: 0755-8188 8998 传真: 0755-26582680 Adress: Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China Tel: +86 755 8188 8998 Fax: +86 755 26582680 Website: www.mindray.com





符合/Pass

质控品检测值应在其参考范围内 靶值范围/ target range: 130(109~151)mg/L Testing results of Quality control

should be within target range.

Control L:测试结果1: 126.59; 测试结果2: 125.39; 测试结果3:

瓶内SD/ SD within<25.0 mg/L或瓶内CV%/

CV% within<5.0%

Control H:SD:3.1 CV:0.6%

瓶内均一性 Inter-vial homogeneity

瓶内SD/ SD within<25.0 mg/L或瓶内CV%/

CV% within<5.0%

Control L:SD:0.6 CV:0.5%

结论

Summary

合格/PASS

备注

Remarks

检验: 徐江明Xu

Analysis Jiangming

日期: Date

2025-05-11

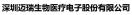
| Xu Jing ming | 批准 (检验工程师): 黄小凤Hua | Approved by(Quality Engineer) | Xi aof eng

黄小凤Huang

日期: Date

2025-05-11

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