检 验 报 告
Certificate of Analysis

No. COA20250123061

产品名称 Product Name	总β人绒毛膜促性腺激素校准品 Total β HCG Calibrators	**REF**	N/A
批号 Lot No.	2024120111	**型号 Model of the Reagent**	N/A
物料编码 Material Code	105-004290-00	**包装规格 Package Size**	C0:1×2.0 mL,C1:1×2.0 mL,C2:1×2.0 mL
生产日期 Manufacture Date	2025-01-22	**有效期 Expiry date**	2026-01-21
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			
外观和性状 Appearance	校准品为清澈透明液体，无沉淀、无悬浮物、无絮状物;分装瓶为白色塑料瓶，盖有塑料外盖;盒贴、瓶贴、标签标识、说明书、校准卡完整、清晰牢固;标贴信息正确、完整;塑料外盖与塑料瓶身配合后无泄漏；塑料外盖无明显划痕、崩缺。 The calibrators are clear liquid without precipitate, suspension and floccules. The containers are white plastic bottles with tightly closed caps;The package, including the labels, introduction, calibration card are complete and clear. The content of labels is correct and complete.The containers are without leakage and obvious defect or breakdown.	符合标准/Qualified	符合/Pass
2、装量 Volume			
装量 Volume	C0≥2.0mL	2.1 mL	符合/Pass
	C1≥2.0mL	2.1 mL	

深圳迈瑞生物医疗电子股份有限公司
SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO.,LTD.
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	C2≥2.0mL	2.1 mL	

3、性能
Performance

	CV≤8%或SD≤0.5 mIU/mL CV≤8% or SD≤0.5 mIU/mL	HCGII 1.5-CO:CV:47%;SD:0.0	
瓶内均一性 Uniformity in bottle	CV≤8%或SD≤0.5 mIU/mL CV≤8% or SD≤0.5 mIU/mL	HCGII 1.5-C1:CV:1%;SD:1.0	符合/Pass
	CV≤8%或SD≤0.5 mIU/mL CV≤8% or SD≤0.5 mIU/mL	HCGII 1.5-C2:CV:1%;SD:26.7	
生物安全性 Biosafety	乙型肝炎病毒表面抗原、人类免疫缺陷病毒抗体（HIV-I型和HIV-II型）、丙型肝炎病毒抗体、梅毒螺旋体抗体检测结果均为阴性。 The calibrators are free from Hepatitis B Surface Antigen (HBsAg), antibody to HIV-1/HIV-2, antibody to Hepatitis C (HCV), and Treponema Pallidum (TP) by using the CE-marked or equivalent method.	阴性/Negative	符合/Pass
赋值准确性 Accuracy	通用机型	通用机型	符合/Pass
	偏倚应在±10.0%范围内。 The bias of trueness control sample is less than ±10.0%.	HCG-H:-5.6%	
	偏倚应在±10.0%范围内。 The bias of trueness control sample is less than ±10.0%.	HCGII 1.0-H:0.3%	
	偏倚应在±10.0%范围内。 The bias of trueness control sample is less than ±10.0%.	HCGII 1.0-L:4.1%	
	偏倚应在±10.0%范围内。 The bias of trueness control sample is less than ±10.0%.	HCGII 1.5-H:0.7%	

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偏倚应在±10.0%范围内。
The bias of trueness control sample is less than ±10.0%.

HCGII 1.5-L:2.7%

偏倚应在±10.0%范围内。
The bias of trueness control sample is less than ±10.0%.

HCG-L:-3.9%

CL-8000i机型

CL-8000i机型

偏倚应在±10.0%范围内。
The bias of trueness control sample is less than ±10.0%.

HCGII 1.0-H:0.9%

偏倚应在±10.0%范围内。
The bias of trueness control sample is less than ±10.0%.

HCGII 1.0-L:0.3%

偏倚应在±10.0%范围内。
The bias of trueness control sample is less than ±10.0%.

HCGII 1.5-H:-3.2%

偏倚应在±10.0%范围内。
The bias of trueness control sample is less than ±10.0%.

HCGII 1.5-L:-1.6%

结论
Summary

合格/PASS

备注
Remarks

检验： **Analysis**	陈素兰Chen Sulan	陈素兰 Chen Sulan	**批准（检验工程师）：** **Approved by(Quality Engineer)**	林朋Lin Peng	林朋 Linpeng
日期： **Date**	2025-01-23		**日期：** **Date**	2025-01-23	

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