

CERTIFICATE OF ANALYSIS

Catalog Number:	G520030	Lot Number:	25041122
Product:	Gel Clot Lyophilized Amebocyte Lysate Multi-test Vial (50 Tests/Vial)	Manufacture Date:	05-Apr-2025
Specifications	5.2 ml/vial	Expiration Date:	04-Apr-2027
Test Items	Description	Results	
Appearance	White lyophilized powder	Pass	
Sensitivity	Within 50% to 200% of specified sensitivity	Pass	
Buffer capacity	pH 6.0-8.0	Pass	
4h negative control	Negative	Pass	
Matched Endotoxin	Lot No. 25045128, 90EU/vial;		
Storage	2-8°C		

The sensitivity of reagent is 0.03 EU/ml when assay parallel with USP/China Pharmacopoeia Reference Standard Endotoxin. Lot No.:H0K354/150800-201601.

Reference:

United States Pharmacopoeia (USP), General Chapter <85>, Bacterial Endotoxins Test (BET) and China Pharmacopoeia <2020 version>, volume 4, general rules 1143.

Operator

Sandy xiao

Date

2025-04.12

QA Administrator

Jane Lin

Date

2025.04.12

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