

CERTIFICATE OF ANALYSIS

Catalog Number: KT0828S **Lot Number:** 25120317
Product: Bioendo™ KT Endotoxin Test Kit
(Kinetic Turbidimetric Assay), 208 Tests/Kit **Expiration Date:** 07-Dec-2027

Contents	Description	Catalog No.	Lot No.
Lyophilized Amebocyte Lysate	2.8ml/vial	KT28S	25124140
Reconstitution Buffer	3.0ml/vial	KTRB30	25128225
Water for BET	50ml/bottle	TRW50S	25126138
Control Standard Endotoxin	Bacterial Strain: <i>E.coli</i> O111:B4	CSE10V	25125249
CSE Reconstituted is 50EU/ml			
CSE Reconstitution Volume (ml)	2.0		
Test (Method)	Specifications		Results
Linearity	r ≥0.98		Pass
Enzyme Activity (Reaction Time)			
Blank-0.005EU/ml	≥ 120 seconds		Pass
0.005EU/ml	≤ 5100 seconds		Pass
1.0EU/ml	≤ 1500 seconds		Pass
Coefficient of Variation (%)	≤ 10%		Pass

Reconstitute CSE with 2.0 ml Water for BET. Mix vigorously for 5 minutes on a vortex mixer, obtaining 50 EU/ml standard stock solution. Reconstituted endotoxin is stable for up to 7 days at 2 to 8° C.

The endotoxin level is 100EU/vial when assay parallel with USP Reference Standard Endotoxin Lot No.: R172R0.

Operator Leichen Yan

Date 2025.12.25

QA Administrator Anlin Ge

Date 2025.12.25