



CERTIFICATE OF ANALYSIS

Catalog Number: KT0828S **Lot Number:** 23040163
Product: Bioendo KT Endotoxin Test Kit
(Kinetic Turbidimetric Assay), 208 Tests/Kit **Expiration Date:** 09-Apr-2025

Contents	Description	Catalog No.	Lot No.
Lyophilized Amebocyte Lysate	2.8ml/vial	KT28S	23044109
Reconstitution Buffer	3.0ml/vial	KTRB30	23028114
Water for BET	50ml/vial	TRW50	23016100
Control Standard Endotoxin	Bacterial Strain: <i>E.coli</i> O111:B4	CSE10V	23015101
CSE Reconstituted is 50EU/ml			
CSE Reconstitution Volume (ml)	2.8		
Test (Method)	Specifications	Results	
Linearity	$ r \geq 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 (%)	$\leq 10\%$	Pass	

Reconstitute CSE with 2.8 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 140EU/vial when assay parallel with USP Reference Standard Endotoxin Lot No.: H0K354.

Operator *Lechen Kan*

Date *2023.04.14*

QA Administrator *Amber Lee*

Date *2023.04.14*