

CERTIFICATE OF ANALYSIS

Catalog Number: KT0828S **Lot Number:** 24030143
Product: Bioendo™ KT Endotoxin Test Kit
(Kinetic Turbidimetric Assay), 208 Tests/Kit **Expiration Date:** 18-Mar-2026

Contents	Description	Catalog No.	Lot No.
Lyophilized Amebocyte Lysate	2.8ml/vial	KT28S	24034112
Reconstitution Buffer	3.0ml/vial	KTRB30	24038131
Water for BET	50ml/vial	TRW50	24016100
Control Standard Endotoxin	Bacterial Strain: <i>E.coli</i> O111:B4	CSE10V	23115202
CSE Reconstituted is 50EU/ml			
CSE Reconstitution Volume (ml)	2.8		
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 2.8 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 Yam

Date 2024.03.20

QA Administrator Kevin Que

Date 2024.03.20