

CERTIFICATE OF ANALYSIS

Catalog Number: KC0828 **Lot Number:** 24110277
Product: Bioendo™ KC Endotoxin Test Kit
(Kinetic Chromogenic Assay) **Expiration Date:** 13-Nov-2026
208 Tests/Kit

Contents	Description	Catalog No.	Lot No.
Kinetic Chromogenic TAL	2.8ml/vial-	KC28	24113013
TAL Reconstitution Buffer	3.0 ml/vial	KCRB30	24118180
Water for BET	50ml/vial	TRW50	24076113
Control Standard Endotoxin	Bacterial Strain: <i>E.coli</i> O111:B4	CSE10V	24115187
CSE Reconstituted is 50EU/ml			
CSE Reconstitution Volume(ml)	2.0		
TEST (Method)	SPECIFICATIONS	Results	
Linearity	$ r \geq 0.98$	Pass	
Enzyme Activity (Reaction Time)			
OnSet OD		0.2	
Blank-0.005EU/ml	≥ 200 seconds	Pass	
0.005 EU/ml	≤ 5850 seconds	Pass	
1.0EU/ml	≤ 1800 seconds	Pass	
Coefficient of Variation (%)	$\leq 10\%$	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.: H0K354.

Operator *Xiang Ying Zhu*

Date *2024.11.21*

QA Administrator *Shenbin Gao*

Date *2024.11.21*