

## CERTIFICATE OF ANALYSIS



<b>Catalog Number:</b>	KT0828S	<b>Lot Number:</b>	22030137
<b>Product:</b>	Bioendo™ KT Endotoxin Test Kit (Kinetic Turbidimetric Assay), 208 Tests/Kit		<b>Expiration Date:</b> 03-Mar-2024

Contents	Description	Catalog No.	Lot No.
Lyophilized Amebocyte Lysate	2.8ml/vial	KT28S	22034105
Reconstitution Buffer	3.0ml/vial	KTRB30	22038112
Water for BET	50ml/vial	TRW50	22016100
Control Standard Endotoxin	Bacterial Strain: <i>E.coli</i> O111:B4	CSE10V	22035110
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 Yan

Date 2022.03.10

QA Administrator Qualin Gao

Date 2022.03.10