

CERTIFICATE OF ANALYSIS

Catalog Number: KC0828 **Lot Number:** 25090267
Product: Bioendo™ KC Endotoxin Test Kit
(Kinetic Chromogenic Assay) **Expiration Date:** 27-Aug-2027
208 Tests/Kit

Contents	Description	Catalog No.	Lot No.
Kinetic Chromogenic LAL	2.8ml/vial	KC28	25093038
Reconstitution Buffer	3.0 ml/vial	KCRB30	25098203
Water for BET	50ml/bottle	TRW50S	25096133
Control Standard Endotoxin	Bacterial Strain: <i>E.coli</i> O111:B4	CSE10V	25095210
CSE Reconstituted is 50EU/ml			
CSE Reconstitution Volume(ml)	1.4		
TEST（Method）	SPECIFICATIONS		Results
Linearity	r ≥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（%）	≤ 10%		Pass

Reconstitute CSE with 1.4 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 70EU/vial when assay parallel with USP Reference Standard Endotoxin Lot No.: H0K354.

Operator Xiang Ying zhu

Date 2015.10.09

QA Administrator [Signature]

Date 2015.10.09