



CERTIFICATE OF ANALYSIS

Catalog Number: EC64405S **Lot Number:** 25120315
Product: Bioendo™ EC Endotoxin Test Kit
(End-point Chromogenic Assay) **Expiration Date:** 07-Dec-2027
64 Tests/Kit

Kit Contents	Description	Catalog No.	Lot No.
Lyophilized Amebocyte Lysate	1.7 ml/vial	EC17	25122038
Control Standard Endotoxin	20EU/vial Bacterial Strain: <i>E.coli</i> O111:B4	CSE10V	25125247
Chromogenic Substrate	1.7 ml/vial	ECCS17	25129058
Stop Reagent	20 ml/vial	ECSR20	25128228
Water for BET	50 ml/bottle	TRW50S	25126138
TEST (Method)	SPECIFICATIONS	Results	
Linearity	$ r \geq 0.98$	Pass	
Coefficient of Variation (%)	≤ 10	Pass	
Endotoxin Range(EU/ml):0.1----1.0			
Enzyme Activity (OD)			
Blank (OD)	≤ 0.20	Pass	
1EU/ml (OD)	≥ 0.75	Pass	
Endotoxin Range(EU/ml):0.01----0.1			
Enzyme Activity (OD)			
Blank (OD)	≤ 0.30	Pass	
0.1EU/ml (OD)	≥ 0.50	Pass	

Recommended Reaction Times for the Assay Kit

Endotoxin Range (EU/ml)	T ₁ (minute)	T ₂ (minute)
0.01 --- 0.1	30	6
0.1 --- 1.0	15	6

Reconstitute CSE with 2.0 ml Water for BET. Mix vigorously for 5 minutes on a vortex mixer, obtaining 10 EU/ml standard stock solution.

The endotoxin level is 20EU/vial when assay parallel with USP Reference Standard Endotoxin Lot No.: R172R0

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Date *2025.12.31*

QA Administrator *Lechen Yan*

Date *2025.12.31*

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