charles river

CERTIFICATE OF ANALYSIS

VIAL CONTENTS: Endosafe® Control Standard Endotoxin is prepared from *E. coli* strain 055:B5. Each vial contains 10 ng of purified Lipopolysaccharide, freeze dried in a stabilized matrix.

RSE/CSE RATIO: The potency of this standard in Endotoxin units, (EU) has been determined to be 17 EU/ng. For **Gel-clot Technique**.

CSE Lot: EX14952 CSE Exp. Date: Apr 2024

LAL Reagent Lot: N3343L LAL Exp. Date: May 2025

RSE Lot: H0K354 RSE/CSE Ratio: 17 EU/ng Vial contents: 170 EU/vial

Geometric Mean Sensitivity with RSE: 0.03 EU/mL

IS/CSE RATIO: The Expert Committee on Biological Standardization of WHO has assigned a potency of the IS as 10,000 IU per vial of IS, so that 1 IU = 1 EU. The potency of this endotoxin standard in International (Endotoxin) Units, IU, has been designated as 17 IU/ng.

DIRECTIONS FOR USE: Reconstitute the lyophilized material with 4.25 mL of LAL reagent grade water to obtain 40 EU/mL or 40 IU/mL. Vortex mix vigorously for at least 5 minutes after rehydration, and for at least 1 minute immediately prior to each use.

STORAGE: Store rehydrated material at 2-8°C for up to 4 weeks. Store lyophilized material at controlled room temperature or refrigerated as preferred. Diluted endotoxin should not be stored except under validated conditions.

CAUTION: DO NOT FREEZE ENDOTOXIN SOLUTIONS

Prepared By: _____ Date: 06 Jan 2022

Quality Reviewed By: _____ Date: 07 JAN 2022