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 20 EU/ng by the method formerly described in Appendix C (***Gel-clot Technique***) of the GUIDELINE ON VALIDATION OF THE LIMULUS AMEBOCYTE LYSATE TEST AS AN END PRODUCT ENDOTOXIN TEST FOR HUMAN AND ANIMAL PARENTERAL DRUGS, BIOLOGICAL PRODUCTS, AND MEDICAL DEVICES, published by the U.S. Food and Drug Administration.

CSE Lot: EX94513 CSE Exp. Date: Feb 2022

LAL Reagent Lot: L1491X LAL Exp. Date: Jun 2022

RSE Lot: H0K354 RSE/CSE Ratio: 20 EU/ng Vial contents: 200 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 20 IU/ng.

DIRECTIONS FOR USE: Reconstitute the lyophilized material with 5.0 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: 25 Jun 2019

Quality Reviewed By: John E. Hall Date: 25 Jun 2019

CA-GC10-06

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