The user of this document is responsible to confirm that the Certificate matches the product of interest.

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 16 EU/ng by the method formerly described in Appendix C (***Kinetic 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: EX14952 CSE Exp. Date: Apr 2024

LAL Reagent Lot: N4193L LAL Exp. Date: Jul 2024

RSE Lot: H0K354 RSE/CSE Ratio: 16 EU/ng Vial contents: 160 EU/vial

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 16 IU/ng.

DIRECTIONS FOR USE: Reconstitute the lyophilized material with 3.2 mL of LAL reagent grade water to obtain 50 EU/mL or 50 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: Ishin Jose Date: 01 Sep 2021

Quality Reviewed By: Jane O'Donnell Date: 06 Sep 2021