



CERTIFICATE OF ANALYSIS

VIAL CONTENTS: Endosafe® Control Standard Endotoxin is prepared from *E. coli* strain 055:B5. Each vial contains 500 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 11 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: EM14902 CSE Exp. Date: Mar 2025

LAL Reagent Lot: N4573L LAL Exp. Date: Aug 2024

RSE Lot: H0K354 RSE/CSE Ratio: 11 EU/ng Vial contents: 5500 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 11 IU/ng.

DIRECTIONS FOR USE: Reconstitute the lyophilized material with 5.5 mL of LAL reagent grade water to obtain 1000 EU/mL or 1000 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: M. Hall Date: 14 Jul 2021

Quality Reviewed By: Bernake Martiny Date: 15 Jul 2021

CA-GC500-07