CSE, 2019

# BIOENDO

### **Control Standard Endotoxin (CSE)**

Catalog number: CSE10

Synonym: Lipopolysaccharide (LPS)

Vial Contents: Freeze dried endotoxin purified from *E.coli* strain O111:B4 in a stabilized matrix.

#### Intended use

Control Standard Endotoxin (CSE) is intended for use to construct standard curves, validate product and prepare inhibition controls in the Tachypleus Amebocyte Lysate (TAL) endotoxin test. The product is for *In Vitro* laboratory purpose only, not for use in human.

The test procedures described herein are conformed to Chapter <85> Bacterial End otoxins, United States Pharmacopeia.

#### Potency

The potency of CSE is referenced against USP Reference Standard Endotoxin (RSE). The potency is expressed as EU/vial, which is labeled on the Certificate of Analysis.

#### Storage

Store lyophilized CSE at 2-8°C . Reconstituted endotoxin solution of potency less than 20EU/ml is stable for up to one day at 2-8°C, for endotoxin solution potency is higher than 20EU/ml, it is stable for at least one week at 2-8°C. Vortex for at least 5 minutes before each use. Diluted endotoxin should not be stored except under validated conditions.

Do not freeze endotoxin solutions.

#### **Reconstitution and Dilution**

Caution: Reconstitute CSE immediately prior to use.

- 1. Gently tap the vial allowing CSE powder to fall to the bottom of the vial, open the vial.
- 2. Reconstitute CSE with TAL Reagent Water(BET Water). The reconstitution volume indicated in the Certificate of Analysis. Mix vigorously for at least 5 minutes on a vortex, obtaining endotoxin stock solution. Dilute endotoxin stock solution into series endotoxin standard solutions as the following example:
- 3. To prepare endotoxin standards at concentrations of 0.0625EU/ml, 0.125EU/ml, 0.25EU/ml, and 0.5EU/ml,

Mix 0.2 ml 10EU/ml of endotoxin with 1.8 ml TAL Reagent Water(BET Water), vortex for 1 minute, obtaining 1EU/ml endotoxin working solution. Mix 1.0 ml 1EU/ml of endotoxin with 1.0 ml TAL Reagent Water(BET Water),

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vortex for 1 minute, obtaining 0.5EU/ml endotoxin, Mix 0.5 ml 1EU/ml of endotoxin with 1.5 ml TAL Reagent Water(BET Water), vortex for 1 minute, obtaining 0.25EU/ml endotoxin, Mix 0.2 ml 1EU/ml of endotoxin with 1.4 ml TAL Reagent Water(BET Water), vortex for 1 minute, obtaining 0.125EU/ml endotoxin, Mix 0.5 ml 0.125EU/ml of endotoxin with 0.5 ml TAL Reagent Water(BET Water), vortex for 1 minute, obtaining 0.0625EU/ml endotoxin.

4. Vortex the endotoxin solution for at least 1 minute immediately prior to each use.

Diluted endotoxin solutions are unstable. Prepare a fresh endotoxin dilution series for every new experiment.

#### Warning:

Product is pyrogenic. Good laboratory technique should be employed in the handling of lipopolysaccharides and Lipid A. Avoid mouth pipetting. Avoid contact with open wounds. Avoid accidental injection.