

ENDOTOXIN (*E. coli* O113:H10) Control Standard Endotoxin (CSE)

For use with Pyrochrome® *Limulus* Amebocyte Lysate (LAL) Chromogenic Test Kit. Store at 2-8°C before reconstitution.

Materials:

- 1) Control Standard Endotoxin (CSE), 10 ng/Vial, (catalog #EC010).
- 2) LAL Reagent Water (LRW). Use sterile water for injection or irrigation (no bacteriostat) or another water certified as an LRW (see lysate package insert).
- 3) Parafilm "M"® (American National Can).
- 4) Disposable glass serological pipettes or micropipettes for the appropriate volumes.
- 5) Dilution tubes (depyrogenated glass tubes or sterile, polystyrene disposables).*

Procedure:

- 1) Remove the crimp seal from the vial.
- 2) Maintain aseptic technique to avoid contaminating the vial and the stopper while opening the vial. Break the vacuum by carefully lifting the edge of the stopper (but do not remove the stopper). Gently tap the vial on the bench to cause loose CSE to fall to the bottom.
- 3) Remove the stopper and aseptically set it aside for reuse – do not discard
- 4) Add LRW to the vial using a pipette. The recommended reconstitution volume is obtained from the Certificate of Analysis, which is specific for the CSE and Pyrochrome lot numbers. Insert stopper back on vial; ensuring that any CSE on stopper is put back into vial.
- 5) Vortex for 30-60 seconds. The CSE will go into the solution immediately. Remove stopper and discard. Cover the vial with Parafilm.
- 6) Store reconstituted CSE at 2-8°C for not more than seven days. Do not freeze reconstituted CSE.
- 7) Prior to using the CSE, bring CSE to room temperature. Vortex the CSE for at least 30 seconds immediately before making the first dilution and then make appropriate dilutions to achieve desired concentrations. Vortex between dilutions.

Potency

Pyrochrome test results should be given in endotoxin units (EU) of U.S. Reference Standard Endotoxin (RSE) per mL. The potency (EU/ng) of CSE is determined by comparison with RSE. Associates of Cape Cod, Inc. determines the potency of CSE with each Pyrochrome test kit. This data is given on a Certificate of Analysis. Please indicate the lot number of CSE and Pyrochrome kit when making a request for a Certificate of Analysis.

The potency of the CSE may also be determined by comparison with any other reference standard (for example, the European or Japanese standards) to convert ng CSE to standard units of alternate reference.

*Disposables should be tested for endotoxin contamination and interference (adsorption and/or extractable) with the LAL test.

Endotoxin

(E. coli O113:H10)

CONTROL STANDARD ENDOTOXIN (CSE)

10 ng/vial

Manufactured by:



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