

Control Standard Endotoxin (CSE)

General Product Description

Control Standard Endotoxin (CSE) is a widely used standard for endotoxin testing. It is a purified extract from *E. coli* O113:H10, the same strain used for the United States Pharmacopeia and the European Pharmacopeia reference standard endotoxin (RSE).

CSE is used as an economic alternative to the RSE. CSEs are standardized against the RSE as indicated on the Certificate of Analysis, so that results can be reported in Endotoxin Units (EU) and International Units (IU). CSE can be used for all LAL testing. A 10 µg/vial CSE is made specifically for use with our Pyrochrome chromogenic reagent.

Depyrogenation Controls

In addition to their use as standards for controlling LAL tests, the 0.5 µg and 125 µg CSEs can be used for validation of depyrogenation processes. They may be used directly, without reconstitution, as depyrogenation indicators (recommended for 0.5 µg) or can be reconstituted and endotoxin added to challenge articles (recommended for 125 µg).

Performing the Test

CSE is used to make standard curves and controls when performing the LAL assay. The concentrations used are dependent on the type of assay (e.g., chromogenic, gel-clot, or turbidimetric) and for photometric methods, the detection range required.

Reconstitution

CSE is reconstituted with LAL Reagent Water (LRW) (or equivalent). Please refer to the Certificate of Analysis when using CSE. A Certificate of Analysis exists for each CSE-lysate lot combination.

Stability

CSE is reconstituted with LRW or equivalent, and is stored at 2–8°C before and after reconstitution. Once reconstituted, the maximum storage time for the different CSE preparations is listed below.

- 10 ng/vial ----- 7 days
 - 0.5 µg/vial ----- 4 weeks
 - 125 µg/vial ----- 3 months
- CSE should not be frozen.*

Packaging

The most commonly used size is 0.5 µg/vial. The 0.5 µg/vial is also used for testing depyrogenation ovens. The 125 µg/vial is typically used for special purposes, e.g., making endotoxin-challenge articles for validation of depyrogenation processes. The 10 ng/vial CSE is available in packs of five vials.

Product Benefits

- CSE is a premium, stable, preparation of endotoxin that can be used in all LAL testing
- CSE is especially useful for depyrogenation studies
- Certificates of Analysis for each CSE-lysate lot pairing gives a potency that is specific to the unique lot combination
- CSE can be reconstituted to achieve specific endotoxin concentrations

For more information please visit our website at www.acciusa.com or contact Technical Services at (800) 848–3248.

- #E0005----- *Escherichia coli* O113:H10, 0.5 µg/vial
- #E0125----- *Escherichia coli* O113:H10, 125 µg/vial
- #EC010----- *Escherichia coli* O113:H10, 10 ng/vial,
5 vials per pack, for use with Pyrochrome®
- #PC010----- Positive Control for Single Test Vial,
0.2 mL LAL and CSE, 10 vials per pack,
CSE concentration is 0.1 ng/mL,
(for research use only)

