

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 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 routine LAL testing. A 10 ng/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 and for photometric methods (chromogenic and turbidimetric), the detection range required.

Reconstitution

CSE is reconstituted with LAL Reagent Water (LRW). Please refer to the Certificate of Analysis when using CSE. A Certificate of Analysis for each CSE-LAL lot combination can be obtained from ACC or online at www.acciusa.com.

Stability

Once reconstituted, CSE stored at 2–8°C is stable for maximum storage time for the different CSE preparations as listed below:

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

Product Benefits

- CSE is a premium, stable, preparation of endotoxin that can be used in all LAL testing
- CSE E0005 and E0125 can be used for depyrogenation studies
- Certificates of Analysis for each CSE-LAL lot pairing gives a potency that is specific to the unique lot combination
- CSE can be reconstituted to achieve specific endotoxin concentrations

Packaging

The 10 ng/vial CSE is available in packs of five vials. Both the 0.5 and 125 µg/vial CSE are sold individually.

Control Standard Endotoxin, *Escherichia coli* O113:H10

#E0005-1	-----	0.5 µg/vial (1 pack)
#E0005-5	-----	0.5 µg/vial (5 pack)
#E0005-25	-----	0.5 µg/vial (25 pack)
#E0125-1	-----	125 µg/vial (1 pack)
#E0125-5	-----	125 µg/vial (5 pack)
#EC010-5	-----	10 ng/vial (5 pack)

For more information please visit our website at www.acciusa.com or contact Customer Service at (508) 540-3444.

