

CERTIFICATE OF ANALYSIS
Standardization of CSE against RSE
Pyrotell® Gel-Clot Method




ACC Internal Control Number: ICQ-0224-072
Test date: 28 FEB 2024

Reagent	Sensitivity (EU/mL)	Catalog No.	Lot No.	Expiration Date (YYYY-MM-DD)
Pyrotell®	0.03	G5003	524-01-007	2029-02-12
Control Standard Endotoxin (CSE), 0.5 µg/vial (= 500 ng/vial)		E0005	184	2027-05-26
Reference Standard Endotoxin (RSE)		N/A	H0K354	N/A

Potency of CSE (per ng)	8 EU/ng or 8 IU/ng
Potency of CSE (per vial)	8 EU/ng x 500 ng/vial = 4,000 EU/vial or 4,000 IU/vial

If the CSE is reconstituted with 5 mL, the endotoxin concentration will be 800 EU/mL.

To obtain a CSE concentration of 1,000 EU/mL, reconstitute the vial with 4.0 mL of LAL Reagent Water.

	28 Feb 24
Quality Control	Date
	11 Mar 24
Quality Assurance	Date
	12 APR 2024
Quality Assurance	Date

Notes:

1. The stated potency applies only to the combination of CSE and LAL lots specified on this certificate.
2. The equivalence of the EU and IU is stated in the USP Bacterial Endotoxins Test chapter, <85>, and in the EP Bacterial Endotoxins chapter, 2.6.14.
3. Potency is subject to change within the error of the test at any time.