

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

ACC Internal Control Number: ICQ-1024-085
Test date: 21 OCT 2024

Reagent	Sensitivity (EU/mL)	Catalog No.	Lot No.	Expiration Date (YYYY-MM-DD)
Pyrotell®	0.03	G5003	523-11-053	2028-12-11
Control Standard Endotoxin (CSE), 0.5 µg/vial (= 500 ng/vial)		E0005	186	2027-11-22
Reference Standard Endotoxin (RSE)		N/A	H0K354	N/A

Potency of CSE (per ng)	10 EU/ng or 10 IU/ng
Potency of CSE (per vial)	10 EU/ng x 500 ng/vial = 5,000 EU/vial or 5,000 IU/vial

If the CSE is reconstituted with 5 mL, the endotoxin concentration will be 1,000 EU/mL.

	
Quality Control	Date
	
Quality Assurance	Date
	
Quality Assurance	Date

Notes:

- The stated potency applies only to the combination of CSE and LAL lots specified on this certificate.
- 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.
- Potency is subject to change within the error of the test at any time.