

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

ACC Internal Control Number: ICQ-0125-053
Test date: 23 JAN 2025

Reagent	Sensitivity (EU/mL)	Catalog No.	Lot No.	Expiration Date (YYYY-MM-DD)
Pyrotell®	0.03	G5003	525-12-001	2030-01-06
Control Standard Endotoxin (CSE), 0.5 µg/vial (= 500 ng/vial)		E0005	187	2028-01-05
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.

	<u>23 Jan 25</u>
Quality Control	Date
	<u>04 Mar 2025</u>
Quality Assurance	Date
	<u>19 MAR 25</u>
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.