

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

ACC Internal Control Number: ICQ-1224-132
Test date: 24 DEC 2024

Reagent	Sensitivity (EU/mL)	Catalog No.	Lot No.	Expiration Date (YYYY-MM-DD)
Pyrotell®	0.03	G5003	524-08-029	2029-08-26
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

27 Dec 24

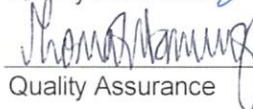
Date



Quality Assurance

02 Jan 25

Date



Quality Assurance

02 Jan 25

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.