

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

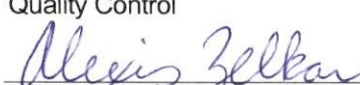
ACC Internal Control Number: ICQ-0326-004
Test date: 02 MAR 2026

Reagent	Sensitivity (EU/mL)	Catalog No.	Lot No.	Expiration Date (YYYY-MM-DD)
Pyrotell®	0.03	G5003	525-10-052	2030-10-17
Control Standard Endotoxin (CSE), 0.5 µg/vial (= 500 ng/vial)		E0005	189	2028-08-15
Reference Standard Endotoxin (RSE)		N/A	R172R0	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.

	03 MAR 26
Quality Control	Date
	03 MAR 26
Quality Assurance	Date
	16 MAR 26
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.