

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





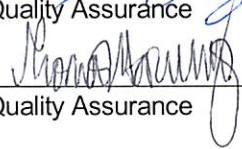

ACC Internal Control Number: ICQ-1222-131  
Test date: 27 DEC 2022

Reagent	Sensitivity (EU/mL)	Catalog No.	Lot No.	Expiration Date (YYYY-MM-DD)
Pyrotell®	0.03	G5003	522-09-040	2027-10-03
Control Standard Endotoxin (CSE), 0.5 µg/vial (= 500 ng/vial)		E0005	180	2025-11-19
Reference Standard Endotoxin (RSE)		N/A	H0K354	N/A

Potency of CSE (per ng)	<b>5 EU/ng</b> or 5 IU/ng
Potency of CSE (per vial)	5 EU/ng x 500 ng/vial = <b>2,500 EU/vial</b> or 2,500 IU/vial

If the CSE is reconstituted with 5 mL, the endotoxin concentration will be 500 EU/mL.

To obtain a CSE concentration of 1,000 EU/mL, reconstitute the vial with 2.5 mL of LAL Reagent Water.

	
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.