


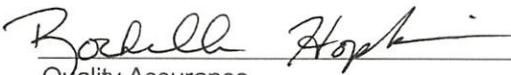

**CERTIFICATE OF ANALYSIS**  
Standardization of CSE against RSE  
Pyrotell® Gel-Clot Method

ACC Internal Control Number: ICQ-1025-149  
Test date: 06 NOV 2025

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	190	2028-08-23
Reference Standard Endotoxin (RSE)		N/A	R172R0	N/A

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

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

	06 NOV 2025
Quality Control	Date
	02 Dec 2025
Quality Assurance	Date
	16 Jan 26
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.