

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


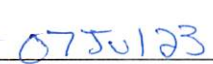


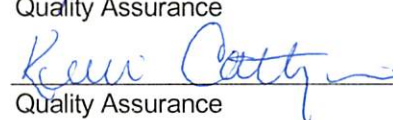
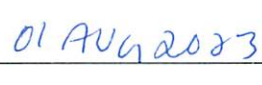
ACC Internal Control Number: ICQ-0723-013  
Test date: 07 JUL 2023

Reagent	Sensitivity (EU/mL)	Catalog No.	Lot No.	Expiration Date (YYYY-MM-DD)
Pyrotell®	0.03	G5003	523-06-027	2028-07-03
Control Standard Endotoxin (CSE), 0.5 µg/vial (= 500 ng/vial)		E0005	182	2026-07-21
Reference Standard Endotoxin (RSE)		N/A	H0K354	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 = <b>4,000 EU/vial</b> 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.

	
Quality Control	Date
	
Quality Assurance	Date
	
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.