

CERTIFICATE OF ANALYSIS
Standardization of CSE against RSE
Pyrotell®-T, Kinetic Turbidimetric Method




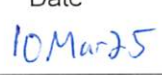


ACC Internal Control Number: ICQ-1224-062
Test date: 19 DEC 2024

Reagent	Catalog No.	Lot No.	Expiration Date (YYYY-MM-DD)
Pyrotell®-T	T0051	524-11-038-T	2029-12-09
Control Standard Endotoxin (CSE), 0.5 µg/vial (= 500 ng/vial)	E0005	187	2028-01-05
Reference Standard Endotoxin (RSE)	N/A	H0K354	N/A

Potency of CSE (per ng)	11 EU/ng or 11 IU/ng
Potency of CSE (per vial)	11 EU/ng x 500 ng/vial = 5,500 EU/vial or 5,500 IU/vial
Valid range of potency	0.001 – 4.0 EU/mL

If the CSE is reconstituted with 5 mL, the endotoxin concentration will be 1,100 EU/mL.

Further dilution will be required to obtain a CSE concentration of 1,000 EU/mL.

	
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.