

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

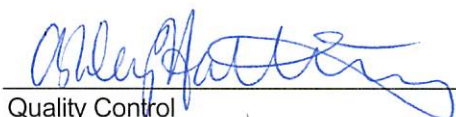
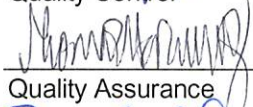

ACC Internal Control Number: ICQ-0223-117
Test date: 23 FEB 2023

Reagent	Catalog No.	Lot No.	Expiration Date (YYYY-MM-DD)
Pyrotell®-T	T0051	522-11-049-T	2027-12-05
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)	16 EU/ng or 16 IU/ng
Potency of CSE (per vial)	16 EU/ng x 500 ng/vial = 8,000 EU/vial or 8,000 IU/vial
Valid range of potency	0.001 – 1.0 EU/mL

If the CSE is reconstituted with 5 mL, the endotoxin concentration will be 1,600 EU/mL.

To obtain a CSE concentration of 1,000 EU/mL, reconstitute the vial with 8.0 mL of LAL Reagent Water.

	27 FEB 2023
Quality Control	Date
	28 Feb 23
Quality Assurance	Date
	01 Mar 2023
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.