

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


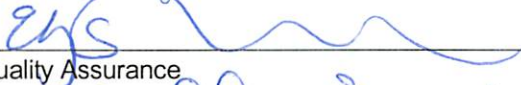

ACC Internal Control Number: ICQ-0722-022  
Test date: 13 JUL 2022

Reagent	Catalog No.	Lot No.	Expiration Date (YYYY-MM-DD)
Pyrotell®-T	T0051	522-06-021-T	2027-06-24
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)	13 EU/ng or 13 IU/ng
Potency of CSE (per vial)	13 EU/ng x 500 ng/vial = <b>6,500 EU/vial</b> or 6,500 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 1,300 EU/mL.

To obtain a CSE concentration of 1,000 EU/mL, reconstitute the vial with 6.5 mL of LAL Reagent Water.

Quality Control		13 JUL 2022
		Date
Quality Assurance		05 AUG 2022
		Date
Quality Assurance		05 AUG 2022
		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.