

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

ACC Internal Control Number: ICQ-1023-075

Test date: 16 OCT 2023



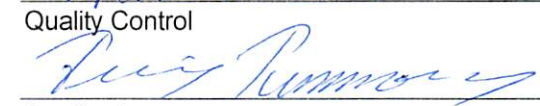
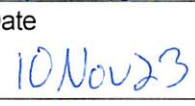

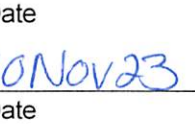
AMENDED

Reagent	Catalog No.	Lot No.	Expiration Date (YYYY-MM-DD)
Pyrotell®-T	T0051	523-07-030-T	2028-08-21
Control Standard Endotoxin (CSE), 0.5 µg/vial (= 500 ng/vial)	E0005	183	2027-03-08
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 = <b>5,500 EU/vial</b> 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:**

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.