

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



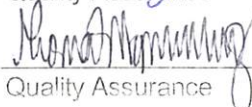
ACC Internal Control Number: ICQ-0126-023
Test date: 12 JAN 2026

Reagent	Catalog No.	Lot No.	Expiration Date (YYYY-MM-DD)
Pyrotell®-T	T0051	524-09-032-T	2029-09-23
Control Standard Endotoxin (CSE), 0.5 µg/vial (= 500 ng/vial)	E0005	190	2028-08-23
Reference Standard Endotoxin (RSE)	N/A	R172R0	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.

	13 JAN 2026
Quality Control	Date
	15 Jan 26
Quality Assurance	Date
	21 Jan 26
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.