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Specialists in Endotoxin and Glucan Detection

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

ACC Internal Control Number: ICQ-0525-090
Test date: 27 MAY 2025

Reagent	Catalog No.	Lot No.	Expiration Date (YYYY-MM-DD)
Pyrotell®-T	T0051	525-04-022-T	2030-05-19
Control Standard Endotoxin (CSE), 0.5 µg/vial (= 500 ng/vial)	E0005	189	2028-08-15
Reference Standard Endotoxin (RSE)	N/A	H0K354	N/A

Potency of CSE (per ng)	9 EU/ng or 9 IU/ng
Potency of CSE (per vial)	9 EU/ng x 500 ng/vial = 4,500 EU/vial or 4,500 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 900 EU/mL.

To obtain a CSE concentration of 1,000 EU/mL, reconstitute the vial with 4.5 mL of LAL Reagent Water.

	28 MAY 25
Quality Control	Date
	12 JUN 25
Quality Assurance	Date
	16 Jun 2025
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.