



Specialists in Endotoxin and Glucan Detection

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

ACC Internal Control Number: ICQ-0824-107




Test date: 28 AUG 2024

Reagent	Catalog No.	Lot No.	Expiration Date (YYYY-MM-DD)
Pyrotell®-T	T0051	524-07-026-T	2029-08-19
Control Standard Endotoxin (CSE), 0.5 µg/vial (= 500 ng/vial)	E0005	187	2028-01-05
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 = <b>8,000 EU/vial</b> or 8,000 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 1,600 EU/mL.

Further dilution will be required to obtain a CSE concentration of 1,000 EU/mL.

	09 SEP 24
Quality Control	Date
	9 Sep 24
Quality Assurance	Date
	12 Sep 24
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.

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