

CERTIFICATE OF ANALYSIS
Standardization of CSE against RSE
Pyrotell® Gel-Clot Method

ACC Internal Control Number: ICQ-0823-006
Test date: 10 AUG 2023

Reagent	Sensitivity (EU/mL)	Catalog No.	Lot No.	Expiration Date (YYYY-MM-DD)
Pyrotell®	0.03	G5003	523-07-032	2028-07-31
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)	10 EU/ng or 10 IU/ng
Potency of CSE (per vial)	10 EU/ng x 500 ng/vial = 5,000 EU/vial or 5,000 IU/vial

If the CSE is reconstituted with 5 mL, the endotoxin concentration will be 1,000 EU/mL.

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Quality Control

Handwritten date: 10 Aug 23

Date

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Quality Assurance

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Date

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Quality Assurance

Handwritten date: 25 AUG 2023

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.