ASSOCIATES OF CAPE COD INCORPORATED

Specialists in Endotoxin and Glucan Detection

CERTIFICATE OF ANALYSIS

Standardization of CSE against RSE
Pyrotell® Gel-Clot Method

ACC Internal Control Number: ICQ-0424-250
Test date: 26 APR 2024

Reagent	Sensitivity (EU/mL)	Catalog No.	Lot No.	Expiration Date (YYYY-MM-DD)
Pyrotell®	0.03	G5003	524-01-007	2029-02-12
Control Standard Endotoxin (CSE), 0.5 µg/vial (= 500 ng/vial)		E0005	186	2027-11-22
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.

Ann Parsons — 26Apr24
Quality Control — Date

Alexis Zelkar — 29Apr24
Quality Assurance — Date

Randee [illegible] — 29APR24
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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