




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

ACC Internal Control Number: ICQ-0424-251
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 | 185 | 2027-10-18 |
| 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.

| | |
|----------------------------------------------------------------------------------------------------------|-------------------|
|  Quality Control | 26 Apr 24 Date |
|  Quality Assurance | 30 Apr 24 Date |
|  Quality Assurance | 30 Apr 24 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.