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Specialists in Endotoxin and Glucan Detection




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

ACC Internal Control Number: ICQ-1123-050
 Test date: 10 NOV 2023

Reagent	Sensitivity (EU/mL)	Catalog No.	Lot No.	Expiration Date (YYYY-MM-DD)
Pyrotell®	0.03	G5003	523-08-038	2028-09-11
Control Standard Endotoxin (CSE), 0.5 µg/vial (= 500 ng/vial)		E0005	184	2027-05-26
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.

	10 Nov 23
Quality Control	Date
	13 Nov 23
Quality Assurance	Date
	14 Nov 23
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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