FUJIFILM

FUJIFILM Wako Chemicals U.S.A. Corporation

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Wako

Certificate of Analysis

*Relationship Between Control Standard Endotoxin (CSE) and Reference Standard Endotoxin (RSE) – **PYROSTAR™ES-F Multi** (Kit)*

RSE:	USP Endotoxin Reference Standard Lot # R172R0, 11,000 EU/vial
CSE:	Control Standard Endotoxin (FUJIFILM Wako Chemicals U.S.A. Corporation)
CSE Lot No.:	G-11USA
Concentration:	500 ng/vial, *E. coli UKT-B*
Tested Against:	***Limulus Amebocyte Lysate*** ***PYROSTAR™ES-F MULTI TEST (5.2 mL)*** ***SENSITIVITY 0.015 EU/mL***
LAL Lot No.:	082508
Production Date:	22 AUG 2025
Sensitivity:	0.015 EU/mL
Expiration Date:	2028.07
Determination Method:	KTA

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Approximate Biological Activity:

EU per Vial:	4,500 EU/vial

Method
Reconstitute the CSE with 4.5 mL LAL Reagent water to get 1,000 EU/mL and vortex for 2 minutes at room temperature. After reconstitution, store CSE at 2→10°C for up to 1 month. DO NOT FREEZE CSE. For subsequent usages, vigorously vortex the solution for 1 minute before use. Vortex each CSE dilution for at least 30 seconds during preparation of dilutions.

Reference
United States Pharmacopeia (USP), 2020, General Chapter <85>, Bacterial Endotoxins Test (BET)
European Pharmacopeia (EP), Chapter 2.6.14, Bacterial Endotoxins

This is to certify that this product lot was manufactured according to current FDA's cGMP Standards which meet FUJIFILM Wako Chemicals U.S.A. Corporation – LAL Division's product specifications and complies with all applicable requirements for product release.

Created By: Caitlin Mirz ***Date:*** *09 / 26 / 2025*

Quality Assurance Approval By: Stephen M. O. Leary ***Date:*** *09 / 26 / 2025*

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