

**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 # H0K354, 10,000 EU/vial
CSE:	Control Standard Endotoxin (FUJIFILM Wako Chemicals U.S.A. Corporation)
CSE Lot No.:	G-78USA
Concentration:	500 ng/vial, <i>E. coli</i> UKT-B
Tested Against:	Limulus Amebocyte Lysate PYROSTAR™ES-F MULTI TEST (5.2 mL) SENSITIVITY 0.125 EU/mL
LAL Lot No.:	111910
Production Date:	27 NOV 2019
Sensitivity:	0.125 EU/mL
Expiration Date:	2022.11
Determination Method:	KTA
<u>Approximate Biological Activity:</u>	
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), 2019, General Chapter <85>, Bacterial Endotoxins Test (BET)	
This is to certify that this product lot was manufactured according to current cGMP Standards, meets FUJIFILM Wako Chemicals U.S.A. – LAL Division's product specifications, and complies with all applicable requirements for product release.	

Created By: Jason Holliday Date: 01 / 23 / 2020Quality Assurance Approval By: Karla Pak Date: 01 / 23 / 2020