

**LAL Division**  
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**Certificate of Analysis**

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

RSE:	USP Endotoxin Reference Standard Lot # HOK354, 10,000 EU/vial
CSE:	Control Standard Endotoxin (Wako Chemicals USA, Inc.)
CSE Lot No.:	G-74USA
Concentration:	500 ng/vial, <i>E. coli</i> UKT-B
Tested Against:	<b><i>Limulus Amebocyte Lysate    PYROSTAR<sup>TM</sup>ES-F MULTI TEST (5.2 mL)    SENSITIVITY 0.03 EU/mL</i></b>
LAL Lot No.:	051909
Production Date:	24 MAY 2019
Sensitivity:	0.03 EU/mL
Expiration Date:	2022.04
Determination Method:	KTA
<u>Approximate Biological Activity:</u>	
EU per Vial:	4,700 EU/vial
<b>Method</b> Reconstitute the CSE with 4.7 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.	
<b>Reference</b> United States Pharmacopeia (USP), 2011, General Chapter <85>, Bacterial Endotoxins Test (BET)	
This is to certify that this product lot was manufactured according to current FDA's cGMP Standards which meets FUJIFILM Wako Chemicals U.S.A. Corporation – LAL Division's product specifications and complies with all applicable requirements for product release.	

Created By: Jason Holliday

Date: 7/22/2019

Quality Assurance  
 Approval By: [Signature]

Date: 7/22/2019