

Certificate of Analysis

Relationship Between Control Standard Endotoxin (CSE) and
Reference Standard Endotoxin (RSE) – **PYROSTARTMES-F Multi** (KIT)

RSE:	USP Endotoxin Reference Standard Lot # HOK354, 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:	<i>Limulus Amebocyte Lysate</i> PYROSTARTMES-F MULTI TEST (5.2 mL) SENSITIVITY 0.06 EU/mL
LAL Lot No.:	091908
Production Date:	26 SEP 2019
Sensitivity:	0.06 EU/mL
Expiration Date:	2022.08
Determination Method:	KTA
<u>Approximate Biological Activity:</u>	
EU per Vial:	5,100 EU/vial

Method

Reconstitute the CSE with 5.1 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: 11/05/2019

Quality Assurance Approval By: Phil Paul Date: 11/05/2019