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Department of Health

Therapeutic Goods Administration

Laboratories Branch

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Title: Bacterial Endotoxin - Appendix 4K - Kinetic CSE Preparation	

Appendix 4K – Kinetic Control Standard Endotoxin (CSE) Preparation

CSE Lot No: 0000837915

CSE expiry date: 30 September 2023

Refer to website of the manufacturer to download the Certificate of Analysis. This will report the correct reconstitution volume. You will need to enter the Catalogue Number (50-650U) and the Lot Number located on the kit box.

The contents of the vial are under vacuum. Remove the vial stopper slowly and carefully to avoid the loss of lyophilised powder.

Reconstitution of CSE		
Amount of LRW	2.7 or (3x900uL)	ml of LAL Reagent Water
LRW Batch Number	0000830072	
Date reconstituted	12 October 2021	
Operator(s):	[REDACTED]	
Reconstituted expiry date:	9 November 2021	(Lonza KQCL- 28 days)

CSE is a specialised biological preparation. For the kinetic assay, the CSE is reconstituted to ensure a starting endotoxin content of 50 EU/ml. The endotoxin potency of each batch of CSE is variable. The manufacturer determines the endotoxin content (EU/ng) using the Reference Standard Endotoxin (RSE) and reports the appropriate reconstitution volume.

Label the CSE vial with the reconstitution date and the expiry date. This is 28 days after reconstitution when stored at 2-8°C.

Secure the reconstituted CSE to a vortex mixer and shake vigorously for a minimum of 15 minutes before each use.