Certificate of Analysis

eShop Dummy Customer US
used in eShop only
BLANCHARD
USA

Print Date: 05-Feb-2021

Product Name: Kinetic-QCL Bulk Kit
100 Vials/Kit
Material Number: K50-643U
Batch No: 0000938258
Manufacturing Date: 30-Sep-2020
Expiration Date: 11-Aug-2022

Test	***RESULT***	***SPECIFICATION MIN***	***MAX***	***UNIT***
K50-643 Matched to E50-643				
Lysate Product Number: K50-643				
Lysate Lot Number	WL006X7RML			
Lysate Sterility				
Bulk	Negative			
Final Container	Negative			
CSE Product Number: E50-643				
CSE Lot Number	0000904567			
Bacterial Strain: E. coli O55:B5				
RSE/CSE Ratio (EU/ng)	7	5	20	
CSE Reconstituted is 50 EU/ml				
1 EU/ml = 1 IU/ml				
CSE Reconstitution Volume (ml)	2.2	1.0	4.0	
Final Release Test:				
Linearity	Pass	***	r < = - 0.980	
Enzyme Activity (Rxn Time)				
Blank - 0.005 EU/ml (sec)	Pass	>=300	***	
0.005 EU/ml (seconds)	Pass	***	<= 5850	
1.0 EU/ml (seconds)	Pass	***	<= 1600	

This lot has been reviewed by Quality Assurance in compliance with requirements of Lonza's Quality System. This document was generated from a validated Part 11-compliant electronic system and thus handwritten signatures are not required.

For Technical Assistance, call 1-800-521-0390

Lonza Walkersville Inc.
8830 Biggs Ford Road
Walkersville, MD 21793 8415
Tel (301) 898 7025
Fax (301) 845 4024

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Test	*RESULT*	*SPECIFICATION MIN*	*MAX*	*UNIT*
Coefficient of Variation (%)	Pass	***	<=10%	

Additional Information:
The FDA has stated that the use of a Certificate of Analysis exempts a firm from having to perform the RSE/CSE comparison in their own laboratories. However, firms should understand exactly how the LAL manufacturer performs the test. The procedure detailed below represents the test method currently used at Lonza. Duplicate samples from independent endotoxin dilution series are prepared from four (4) separate vials of test CSE. These samples are tested against an endotoxin standard curve prepared from the RSE with the specified lot of LAL reagent. The predicted potency, adjusted for dilution, for each CSE dilution falling within the limits of the RSE standard curve is determined. The overall average potency of all such CSE dilutions is used to determine the reconstitution volume to yield an endotoxin solution containing 50 EU/ml.

The Blank - 0.005 EU/ml result is an average of the vials tested.

Leah Baltos
Electronically signed by Leah Baltos
Date: 01-OCT-2020 14:45:05 EST
RELEASE (Inspection Lot: Usage Decision)

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