

## Certificate of Analysis

eShop Dummy Customer US  
 used in eShop only  
 BLANCHARD  
 USA

**Print Date:** 19-May-2020

**Product Name:** Kinetic-QCL Bulk Kit  
 100 Vials/Kit  
**Material Number:** K50-643U  
**Batch No:** 0000893421  
**Manufacturing Date:** 07-Apr-2020  
**Expiration Date:** 25-May-2022

<i>Test</i>	<i>RESULT</i>	<i>SPECIFICATION</i>		<i>UNIT</i>
		<i>MIN</i>	<i>MAX</i>	
K50-643 Matched to E50-643				
Lysate Product Number: K50-643				
Lysate Lot Number	VL119KYEAG			
Lysate Sterility				
Bulk	Negative			
Final Container	Negative			
CSE Product Number: E50-643				
CSE Lot Number	0000830018			
Bacterial Strain: E. coli O55:B5				
RSE/CSE Ratio (EU/ng)	12	5	20	
CSE Reconstituted is 50 EU/ml				
1 EU/ml = 1 IU/ml				
CSE Reconstitution Volume (ml)	3.6	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.

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

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Coefficient of Variation (%)	Pass	***	<=10%	

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**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.

**Susan Thomas**

Electronically signed by Susan Thomas

Date: 08-APR-2020 13:28:27 EST

RELEASE ( Inspection Lot: Usage Decision )

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

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