Certificate of Analysis

eShop Dummy Customer US
used in eShop only
BLANCHARD
USA

Print Date: 08-Dec-2020

Product Name: Pyrogent-5000 Bulk Kit
2250 Test Kit
Material Number: N588
Batch No: 0000938268
Manufacturing Date: 02-Oct-2020
Expiration Date: 17-Dec-2021

Test	*RESULT*	*SPECIFICATION MIN*	*MAX*	*UNIT*
Lysate Product Number: T50-300				
Lysate Lot Number	VL128UAF2U			
Lysate Sterility:				
Bulk	Negative	NEGATIVE	***	
Final Container	Negative	NEGATIVE	***	
CSE Product Number: 7460				
CSE Lot Number	0000858022			
Bacterial Strain: E. coli O55:B5				
CSE Reconstituted is 100 EU/ml				
1 EU/ml = 1 IU/ml				
RSE/CSE Ratio (EU/ng)	7	***	***	
CSE Reconstitution Volume (ml)	3.7	2.0	10.0	
Final Release Test:				
Linearity	Pass	***	< = - 0.980	
Enzyme Activity (Reaction Time)				
Blank - 0.01 EU/ml (seconds)	Pass	>= 300	***	
0.01 EU/ml (seconds)	Pass	***	<= 5100	
1.0 EU/ml (seconds)	Pass	***	<= 1500	
Coefficient of Variation (%)	Pass	***	< = 10	

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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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 100 EU/ml.

Susan Thomas
Electronically signed by Susan Thomas
Date: 06-OCT-2020 14:35:11 EST
RELEASE (Inspection Lot: Usage Decision)

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