

## Certificate of Analysis

eShop Dummy Customer US  
used in eShop only  
BLANCHARD  
USA

**Print Date:** 12-May-2021

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**Product Name:** PyroGene 192 Test Kit  
**Material Number:** 50-658U  
**Batch No:** 0000958024  
**Manufacturing Date:** 09-Dec-2020  
**Expiration Date:** 01-Oct-2021

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<i>Test</i>	<i>RESULT</i>	<i>SPECIFICATION</i>		<i>UNIT</i>
		<i>MIN</i>	<i>MAX</i>	
rFC Product Number: R50-658				
rFC Lot Number	WL027NBBY3			
rFC Sterility				
Bulk	Negative	NEGATIVE	***	
Final Container	Negative	NEGATIVE	***	
CSE Product Number: E50-643				
CSE Lot Number	0000920758			
Bacterial Strain: E. coli O55:B5				
CSE Reconstituted is 20 EU/ml				
1 EU/ml = 1 IU/ml				
CSE Reconstitution Volume (ml)	4.5	Test & Report	***	
Final Release Test:				
rFC Linearity	Pass	r >= 0.980	***	
rFC CV%	Pass	***	<= 20	
Blank	Pass	***	<250	
0.005 EU/ml	Pass	>10	***	
Slope	Pass	0.76	1.11	
Sample PPC	Pass	50%	200%	

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 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 containing 20 EU/ml.

**Leah Baltos**

Electronically signed by Leah Baltos

Date: 15-DEC-2020 07:32:49 EST

RELEASE ( Inspection Lot: Usage Decision )

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