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Lonza

CERTIFICATE OF ANALYSIS

Product Code: 50-650NV
Product: Kinetic-QCL Bulk Kit
2040 Test Kit

Lot Number: 0000756909
Manufacture Date: 18-Oct-2018
Expiration Date: 17-Mar-2021

TEST (Method)	SPECIFICATIONS Min.	Max.	Results
Lysate Product Number: K50-643			
Lysate Lot Number			UL110QADXX
Lysate Sterility:			
Bulk	NEGATIVE	***	Negative
Final Container	NEGATIVE	***	Negative
CSE Product Number: E50-643			
CSE Lot Number			0000742512
Bacterial Strain: E. coli O55:B5			
RSE/CSE Ratio (EU/ng)	***	***	10
CSE Reconstituted is 50 EU/ml			
1 EU/ml = 1 IU/ml			
CSE Reconstitution Volume (ml)	***	***	3.4
Final Release Test:			
Linearity	***	r < = - 0.980	Pass
Enzyme Activity (Rxn Time)			
Blank - 0.005 EU/ml (sec)	>=300	***	Pass
0.005 EU/ml (seconds)	***	<= 5850	Pass
1.0 EU/ml (seconds)	***	<= 1600	Pass
Coefficient of Variation (%)	***	<= 10%	Pass

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.

This lot has been reviewed by Quality Assurance in compliance with requirements of Lonza's Quality System.
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