

Certificate of Analysis

eShop Dummy Customer CH
used in eShop only
CH-

Print Date: 03-Dec-2019

Product Name: QCL-1000 120 Test Kit
Material Number: 50-647U
Batch No: 0000854254
Manufacturing Date: 30-Oct-2019
Expiration Date: 29-Oct-2021

| <i>Test</i> | <i>RESULT</i> | <i>SPECIFICATION</i> | | <i>UNIT</i> |
|-----------------------------------|---------------|----------------------|------------|-------------|
| | | <i>MIN</i> | <i>MAX</i> | |
| Lysate Product Number: 50-641W | | | | |
| Lysate Lot Number | 0000838016 | | | |
| Lysate Sterility: | | | | |
| Bulk | Negative | NEGATIVE | *** | |
| Final Container | Negative | NEGATIVE | *** | |
| CSE Product Number: E50-640 | | | | |
| CSE Lot Number | 0000751099 | | | |
| Bacterial Strain: E. coli O111:B4 | | | | |
| CSE Reconst. Potency (EU/ml) | 23 | *** | *** | |
| 1 EU/ml = 1 IU/ml | | | | |
| Final Release Test: | | | | |
| Linearity for 16 Minute Assay | Pass | *** | r >= 0.980 | |
| Enzyme Activity (OD) | | | | |
| Blank (OD) | Pass | *** | < = 0.15 | |
| 1 EU/ml (OD) | Pass | >= 0.75 | *** | |
| 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

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

Certificate of Analysis

eShop Dummy Customer CH
used in eShop only
CH-

Print Date: 03-Dec-2019

Product Name: QCL-1000 120 Test Kit
Material Number: 50-647U
Batch No: 0000854254
Manufacturing Date: 30-Oct-2019
Expiration Date: 29-Oct-2021

| <i>Test</i> | <i>RESULT</i> | <i>SPECIFICATION</i> | | <i>UNIT</i> |
|--------------------|----------------------|-----------------------------|-------------------|--------------------|
| | | <i>MIN</i> | <i>MAX</i> | |

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 labeled EU potency on the Certificate of Analysis is the overall average potency of all such CSE dilutions.

Raj Patel

Electronically signed by Raj Patel

Date: 01-NOV-2019 15:55:04 EST

RELEASE (Inspection Lot: Usage Decision)

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