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Lonza

CERTIFICATE OF ANALYSIS

Product Code: N494-03
Product: PYROGENT Plus 4000 Tests
0.03 EU/ml Sensitivity

Lot Number: 0000723893
Manufacture Date: 08-Jun-2018
Expiration Date: 12-Apr-2021

TEST (Method)	SPECIFICATIONS Min.	Max.	Results
Lysate Product Number: E194-03			
Lysate Lot Number			0000705163
Lysate Sterility:			
Bulk	NEGATIVE	***	Negative
Final Container	NEGATIVE	***	Negative
CSE Product Number: 7360			
CSE Lot Number			0000672058
Bacterial Strain: E. coli O55:B5			
RSE/CSE Ratio (EU/ng)	***	***	5
CSE Reconst. Potency (EU/ml)	10	40	10
1 EU/ml = 1 IU/ml			
Final Release Test:			
Sensitivity	PASS	***	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. Quadruplicate samples from independent two-fold dilution series are prepared from four (4) separate vials of test CSE. The samples are used in parallel with one (1) dilution series from a single vial of each RSE and are tested with the specified lot of LAL reagent. The labeled EU/ml potency on the Certificate of Analysis is calculated from the ratio of the geometric average endpoint dilution of the RSE and CSE.

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