b|e|i RESOURCES

SUPPORTING INFECTIOUS DISEASE RESEARCH

Certificate of Analysis for NR-14697

Influenza A Virus, A/New York/18/2009 (H1N1)pdm09, BPL-Inactivated

Catalog No. NR-14697

Product Description: NR-14697 is a preparation of influenza A virus, A/New York/18/2009 (H1N1)pdm09 that has been inactivated with beta-propiolactone (BPL). The source virus used for the inactivation was BEI Resources NR-14694, Lot No. 58690675.

Lot: 59300926 **Manufacturing Date: 22JUN2010**

TEST	SPECIFICATIONS	RESULTS
Innocuity Test (Screening for Viral Inactivation in Eggs)[1,2]		
NR-14697, Influenza A Virus, A/New York/18/2009 (H1N1)pdm09, BPL-inactivated[3]		
1st round of amplification (1:10)	No HA activity detected	No HA activity detected
2nd round of amplification (neat)	No HA activity detected	No HA activity detected
3rd round of amplification (neat)	No HA activity detected	No HA activity detected
NR-14694, Influenza A Virus, A/New York/18/2009 (H1N1)pdm09 Positive Control		
1st round of amplification (1:10)	HA activity detected	HA activity detected
2nd round of amplification (1:10)	HA activity detected	HA activity detected
3rd round of amplification (1:10)	HA activity detected	HA activity detected
Functional Activity		
RNA detection by PCR of extracted Test Article nucleic acid		
Influenza A virus primer and probe set	Detected	Detected
Influenza pandemic H1 primer and probe set	Detected	Detected[4]
Influenza H1 primer and probe set	None detected	None detected[4]
Influenza H3 primer and probe set	None detected	None detected
Influenza H5a primer and probe set	None detected	None detected
Influenza H5b primer and probe set	None detected	None detected
Influenza B virus primer and probe set	None detected	None detected
Antigenicity using BD™ Directigen™ EZ Flu A+B (Cat. No. 256050)		
Influenza A	Report results	Reactive
Influenza B	Report results	Non-reactive
Sterility (21-day incubation)		
Harpo's HTYE broth[4], 37°C and 26°C, aerobic	No growth detected	No growth detected
Trypticase soy broth, 37°C and 26°C, aerobic	No growth detected	No growth detected
Sabouraud broth, 37°C and 26°C, aerobic	No growth detected	No growth detected
Sheep blood agar, 37°C, aerobic	No growth detected	No growth detected
Sheep blood agar, 37°C, anaerobic	No growth detected	No growth detected
Thioglycollate broth, 37°C, anaerobic	No growth detected	No growth detected
DMEM with 10% FBS, 37°C and 5% CO_2	No growth detected	No growth detected
Mycoplasma Contamination		
DNA detection by PCR of extracted Test Article nucleic acid	None detected	None detected

[1]9- to 11-day-old embryonated chicken eggs were inoculated with 0.2 mL of the indicated test sample and incubated at 35°C for 2 days. Allantoic fluid from the first round of amplification was tested for HA activity and 0.2 mL was inoculated into 9- to 11-day-old embryonated chicken eggs and incubated at 35°C for 2 days. Allantoic fluid from the second round of amplification was tested for HA activity and 0.2 mL was inoculated into 9- to 11-day-old embryonated chicken eggs and incubated at 35°C for 2 days. Allantoic fluid from the third round of amplification was tested for HA activity.

[2]The inoculum for the first round of amplification for the Positive Control (NR-14694) was 3.2×10^6 $CEID_{50}$ per egg. The inoculum for the first round of amplification for the BPL-inactivated Test Article (NR-14697) was 2.8×10^6 $CEID_{50}$ equivalents per egg.

[3]Bulk BPL-inactivated virus tested prior to vialing.

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[4]Influenza A virus, A/New York/18/2009 (H1N1)pdm09 is a pandemic strain that is not readily detected using the CDC seasonal H1 primer/probe set.
[5]Atlas, Ronald M. Handbook of Microbiological Media. 3rd ed. Ed. Lawrence C. Parks. Boca Raton: CRC Press, 2004, p. 798.

Date: 07 JUN 2013 **Signature:** Dorothy C. Young

Title: Technical Manager, BEI Authentication or designee

ATCC®, on behalf of BEI Resources, hereby represents and warrants that the material provided under this certificate has been subjected to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and accurate to the best of ATCC®'s knowledge.

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