

Certificate of Analysis for NR-18924

Influenza B Virus, B/Florida/4/2006, BPL-Inactivated

Catalog No. NR-18924

Product Description:

NR-18924 is a preparation of Influenza B Virus, B/Florida/4/2006 (lot 58155275) that has been inactivated with beta-propiolactone (BPL), frozen as bulk, thawed, diluted 1:200 in DPBS and dispensed on 24MAY2023 to produce lot 70060722.

Lot: 70060722 Manufacturing Date: 11SEP2009

TEST	SPECIFICATIONS	RESULTS
Pre-Inactivation Titer by CEID₅₀ Assay in Embryonated Chicken		1.233213
Eggs ¹	Report results	2.8 × 10 ⁸ CEID ₅₀ /mL
(2 days at 33°C with humidity)	Troport results	2.0 · 10 OLID30/IIIL
Bulk Innocuity Test (Screening for Viral Inactivation in Eggs) ^{2,3}		
NR-18924, Influenza B Virus, B/Florida/4/2006, BPL-inactivated ⁴		
1 st round of amplification (1:10)	No HA activity detected	No HA activity detected
2 nd round of amplification (neat)	No HA activity detected	No HA activity detected
3 rd round of amplification (neat)	No HA activity detected	No HA activity detected
NR-9696, Influenza B Virus, B/Florida/4/2006, Positive Control		-
1 st round of amplification (1:10)	HA activity detected	HA activity detected
2 nd round of amplification (1:10)	HA activity detected	HA activity detected
3 rd round of amplification (1:10)	HA activity detected	HA activity detected
Bulk Post-Inactivation Mycoplasma Contamination ³		
Agar and broth culture (14-day incubation at 37°C)	None detected	None detected
DNA detection by PCR of extracted Test Article nucleic acid	None detected	None detected
Functional Activity ⁴		
RNA detection by qPCR of extracted Test Article nucleic acid		
Influenza B virus primer and probe set	Detected	Detected
Post-Inactivation Sterility (21-day incubation) ⁴		
Harpo's HTYE broth, 37°C and 26°C, aerobic ⁵	No growth	No growth
Trypticase soy broth, 37°C and 26°C, aerobic	No growth	No growth
Sabouraud broth, 37°C and 26°C, aerobic	No growth	No growth
Sheep blood agar, 37°C, aerobic	No growth	No growth
Sheep blood agar, 37°C, anaerobic	No growth	No growth
Thioglycollate broth, 37°C, anaerobic	No growth	No growth
DMEM with 10% FBS, 37°C, aerobic	No growth	No growth

¹The Chicken Embryo Infectious Dose 50% (CEID₅₀) is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the inoculated embryonated chicken eggs, just as a Lethal Dose 50% (LD50) is expected to kill half of the animals exposed. A reciprocal of the dilution required to yield the CEID₅₀ provides a measure of the infectious titer (or infectivity) of a virus preparation.

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²⁹- 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.

³Test performed on bulk BPL-treated virus prior to dilution and vialing.

⁴Test performed on BPL-treated virus after dilution and vialing.

⁵Atlas, Ronald M. <u>Handbook of Microbiological Media</u>. 3rd ed. Ed. Lawrence C. Parks. Boca Raton: CRC Press, 2004, p. 798.



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/Sonia Bjorum Brower/ Sonia Bjorum Brower

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Technical Manager or designee, ATCC Federal Solutions

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