

Influenza B Virus, B/Malaysia/2506/2004, BPL-Inactivated

Catalog No. NR-19324

Product Description: NR-19324 is a preparation of influenza B virus, B/Malaysia/2506/2004 that has been inactivated with beta-propiolactone (BPL). The source virus used for the inactivation was BEI Resources NR-9723, Lot No. 58155277.

Lot: 59405632

Manufacturing Date: 21JUL2010

TEST	SPECIFICATIONS	RESULTS
Innocuity Test (Screening for Viral Inactivation in Eggs)¹⁻³ NR-19324, Influenza B Virus, B/Malaysia/2506/2004, BPL-inactivated ³ 1 st round of amplification (1:10) 2 nd round of amplification (neat) 3 rd round of amplification (neat) NR-9723, Influenza B Virus, B/Malaysia/2506/2004 Positive Control 1 st round of amplification (1:10) 2 nd round of amplification (1:10) 3 rd round of amplification (1:10)	No HA activity detected No HA activity detected No HA activity detected HA activity detected HA activity detected HA activity detected	No HA activity detected No HA activity detected No HA activity detected HA activity detected HA activity detected HA activity detected
Functional Activity RNA Detection by PCR of Extracted Test Article Nucleic Acid ⁴ Influenza A virus primer and probe set Influenza H1 seasonal primer and probe set Influenza H3 primer and probe set Influenza H5a primer and probe set Influenza H5b primer and probe set Influenza B virus primer and probe set Antigenicity using BD™ Directigen™ EZ Flu A+B (Cat. No. 256050) ⁵ Influenza A Influenza B	None detected None detected None detected None detected None detected None detected Detected Report results Report results	None detected None detected None detected None detected None detected None detected Detected Non-reactive Reactive
Mycoplasma Contamination DNA detection by PCR of extracted Test Article nucleic acid	None detected	None detected

¹9- to 11-day old embryonated chicken eggs were inoculated with 0.2 mL of the indicated test sample and incubated at 33°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 33°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 33°C for 2 days. Allantoic fluid from the third round of amplification was tested for HA activity.

²The inoculum for the first round of amplification for the Positive Control (NR-9723) was 3.2 x 10⁵ CEID₅₀ per egg. The inoculum for the first round of amplification for the BPL-inactivated Test Article (NR-19324) was 2.8 x 10⁴ CEID₅₀ equivalents per egg.

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

⁴Using Influenza Virus Real-Time RT-PCR Assay (BEI Resources NR-15614)

⁵Test performed on bulk material prior to vialing

Date: 16 NOV 2015

Signature: 

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