

**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 that has been inactivated with beta-propiolactone (BPL). The source virus used for the inactivation was BEI Resources NR-9696, Lot No. 58155275.

**Lot: 59192548**

**Manufacturing Date: 02JUN2010**

TEST	SPECIFICATIONS	RESULTS
<b>Innocuity Test (Screening for Viral Inactivation in Eggs)<sup>1,2</sup></b> NR-18924, Influenza B virus, B/Florida/4/2006, BPL-inactivated <sup>3</sup> 1 <sup>st</sup> round of amplification (1:10) 2 <sup>nd</sup> round of amplification (neat) 3 <sup>rd</sup> round of amplification (neat) NR-9696, Influenza B virus, B/Florida/4/2006, Positive Control 1 <sup>st</sup> round of amplification (1:10) 2 <sup>nd</sup> round of amplification (1:10) 3 <sup>rd</sup> 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
<b>Functional Activity</b> RNA detection by PCR of extracted Test Article nucleic acid Influenza A virus primer and probe set Influenza H1 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) <sup>3</sup> 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
<b>Sterility (21-day incubation)</b> Harpo's HTYE broth <sup>4</sup> , 37°C and 26°C, aerobic Trypticase soy broth, 37°C and 26°C, aerobic Sabouraud broth, 37°C and 26°C, aerobic Sheep blood agar, 37°C, aerobic Sheep blood agar, 37°C, anaerobic Thioglycollate broth, 37°C, anaerobic DMEM with 10% FBS, 37°C and 5% CO <sub>2</sub>	No growth detected No growth detected No growth detected No growth detected No growth detected No growth detected No growth detected No growth detected	No growth detected No growth detected No growth detected No growth detected No growth detected No growth detected No growth detected No growth detected
<b>Mycoplasma Contamination</b> DNA detection by PCR of extracted Test Article nucleic acid	None detected	None detected

<sup>1</sup>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.

<sup>2</sup>The inoculum for the first round of amplification for the Positive Control (NR-9696) was 5.6 x 10<sup>6</sup> CEID<sub>50</sub> per egg. The inoculum for the first round of amplification for the BPL-inactivated Test Article (NR-18924) was 5.3 x 10<sup>6</sup> CEID<sub>50</sub> equivalents per egg.

<sup>3</sup>Bulk BPL-inactivated virus tested prior to vialing.

<sup>4</sup>Atlas, Ronald M. *Handbook of Microbiological Media*. 3rd ed. Ed. Lawrence C. Parks. Boca Raton: CRC Press, 2004, p. 798.

## Certificate of Analysis for NR-18924

**Date:** 25 JAN 2011

**Signature:** *Dorothy C. Young*

**Title:** Technical Manager, BEI Authentication or designee

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