

**Influenza A Virus, A/Puerto Rico/8/1934 (H1N1), BPL-Inactivated**

**Catalog No. NR-19325**

**Product Description:** NR-19325 is a preparation of influenza A virus, A/Puerto Rico/8/1934 (H1N1) that has been inactivated with beta-propiolactone (BPL). The source virus used for the inactivation was BEI Resources NR-348, Lot No. 4729801.

**Lot: 62138970**

**Manufacturing Date: 02JUN2010**

TEST	SPECIFICATIONS	RESULTS
<b>Concentration (in CEID<sub>50</sub> equivalents)</b>	Report results	2.8 × 10 <sup>8</sup> CEID <sub>50</sub> equivalents per mL
<b>Innocuity Test (Screening for Viral Inactivation in Eggs)<sup>1-3</sup></b> NR-19325, Influenza A Virus, A/Puerto Rico/8/1934, 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-348, Influenza A Virus, A/Puerto Rico/8/1934 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>RNA Detection by PCR of Extracted Test Article Nucleic Acid<sup>4</sup></b> 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	Detected Detected None detected None detected None detected None detected	Detected Detected None detected None detected None detected None detected
<b>Hemagglutination Titer Using 0.5% Chicken Red Blood Cells</b>	Report results	128
<b>Sterility (21-day incubation)</b> Harpo's HTYE broth <sup>5</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 No growth No growth No growth No growth No growth No growth	No growth No growth No growth No growth No growth No growth No growth
<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-348) was 3.2 × 10<sup>7</sup> CEID<sub>50</sub> per egg. The inoculum for the first round of amplification for the BPL-inactivated Test Article (NR-19325) was 2.8 × 10<sup>7</sup> CEID<sub>50</sub> equivalents per egg.

<sup>3</sup>Test performed on bulk BPL-treated virus prior to dilution and vialing

<sup>4</sup>Using Influenza Virus Real-Time RT-PCR Assay (BEI Resources NR-15592)

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

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