

**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 (lot 58690675) that has been inactivated with beta-propiolactone (BPL), frozen as bulk, thawed, diluted 1:200 in DPBS and dispensed 25MAY2023 to produce lot 70060723.

**Lot: 70060723**

**Manufacturing Date: 26MAY2010**

TEST	SPECIFICATIONS	RESULTS
<b>Pre-Inactivation Titer by CEID<sub>50</sub> Assay in Embryonated Chicken Eggs<sup>1</sup></b> (2 days at 35°C with humidity)	Report results	1.6 × 10 <sup>8</sup> CEID <sub>50</sub> /mL
<b>Bulk Innocuity Test (Screening for Viral Inactivation in Eggs)<sup>2,3</sup></b> NR-14697, Influenza A Virus, A/Brisbane/59/2007 (H1N1), BPL-inactivated <sup>4</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-12278, Influenza A Virus, A/Sydney/5/97 (H3N2), 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>Bulk Post-Inactivation Mycoplasma Contamination<sup>3</sup></b> Agar and broth culture (14-day incubation at 37°C) DNA detection by PCR of extracted Test Article nucleic acid	None detected None detected	None detected None detected
<b>Functional Activity<sup>4</sup></b> RNA detection by qPCR of extracted Test Article nucleic acid Influenza A virus primer and probe set Influenza H1 primer and probe set	Detected Detected	Detected Not Detected <sup>5</sup>
<b>Post-Inactivation Sterility (21-day incubation)<sup>4</sup></b> Harpo's HTYE broth, 37°C and 26°C, aerobic <sup>6</sup> 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, aerobic	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 No growth No growth

<sup>1</sup>The Chicken Embryo Infectious Dose 50% (CEID<sub>50</sub>) 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 CEID<sub>50</sub> provides a measure of the infectious titer (or infectivity) of a virus preparation.

<sup>2</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>3</sup>Test performed on bulk BPL-treated virus prior to dilution and vialing.

<sup>4</sup>Test performed on BPL-treated virus after dilution and vialing.

<sup>5</sup>The influenza A-specific primer and probe set detected the appropriate RNA by qPCR. Previous lots and source virus indicate this virus is H1.

<sup>6</sup>Atlas, Ronald M. *Handbook of Microbiological Media*. 3rd ed. Ed. Lawrence C. Parks. Boca Raton: CRC Press, 2004, p. 798.

/Sonia Bjorum Brower/

Sonia Bjorum Brower

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