

Influenza A Virus, A/California/07/2009 (H1N1)pdm09, BPL-Inactivated

Catalog No. NR-13664

Product Description: NR-13664 is a preparation of influenza A virus, A/California/07/2009 (H1N1)pdm09 that has been inactivated with beta-propiolactone (BPL). The source virus used for the inactivation was BEI Resources NR-13663, Lot No. 58632367.

Lot: 59265377

Manufacturing Date: 04JUN2010

TEST	SPECIFICATIONS	RESULTS
Innocuity Test (Screening for Viral Inactivation in Eggs)^{1,2} NR-13664, Influenza A Virus, A/California/07/2009 (H1N1)pdm09, BPL-inactivated ³ 1 st round of amplification (neat) 2 nd round of amplification (neat) 3 rd round of amplification (neat) NR-13663, Influenza A Virus, A/California/07/2009 (H1N1)pdm09 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 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) Influenza A Influenza B	Detected Detected None detected None detected None detected None detected Report results Report results	Detected Detected None detected None detected None detected None detected Reactive Non-reactive
Sterility (21-day incubation) Harpo's HTYE broth ⁴ , 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 ₂	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
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 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.

²The inoculum for the first round of amplification for the Positive Control (NR-13663) was 5.6 × 10⁶ CEID₅₀ per egg. The inoculum for the first round of amplification for the BPL-inactivated Test Article (NR-13664) was 5.3 × 10⁷ CEID₅₀ equivalents per egg.

³Bulk BPL-inactivated virus tested prior to vialing.

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

Certificate of Analysis for NR-13664

Date: 07JUN 2013

Signature: *Dorothy C. Young*

Title: Technical Manager, BEI Authentication or designee

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