

Influenza A Virus, A/Brisbane/10/2007 (H3N2), BPL-Inactivated

Catalog No. NR-19321

Product Description: NR-19321 is a preparation of influenza A virus, A/Brisbane/10/2007 (H3N2) that has been inactivated with beta-propiolactone (BPL).

Lot¹: 70017240

Manufacturing Date: 26MAY2010

TEST	SPECIFICATIONS	RESULTS
Innocuity Test (Screening for Viral Inactivation in Eggs)^{2,3} NR-19321, Influenza A Virus, A/Brisbane/10/2007 (H3N2), BPL-inactivated ⁴ 1 st round of amplification (1:10) 2 nd round of amplification (neat) 3 rd round of amplification (neat) NR-12283, Influenza A Virus, A/Brisbane/10/2007 (H3N2), 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 ⁵ 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 Remel™ Xpect® Flu A+B (Cat. No. R24600) Influenza A Influenza B	Detected None detected Detected None detected None detected None detected Report results Report results	Detected None detected Detected None detected None detected None detected Reactive Non-reactive
Sterility (21-day incubation) Harpo's HTYE broth ⁶ , 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

¹Source virus: BEI Resources NR-12283 lot 58550258

²9- 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.

³The inoculum for the first round of amplification for the Positive Control (NR-12283) was 5.6 x 10⁶ CEID₅₀ per egg. The inoculum for the first round of amplification for the BPL-inactivated Test Article (NR-19321) was 5.0 x 10⁶ CEID₅₀ equivalents per egg.

⁴Test performed on bulk BPL-treated virus prior to dilution and vialing.

⁵Using Influenza Virus Real-Time RT-PCR Assay (BEI Resources NR-15592)

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

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