

Influenza A Virus, A/Brisbane/59/2007 (H1N1), BPL-Inactivated

Catalog No. NR-19322

Product Description:

NR-19322 consists of a preparation of influenza A virus, A/Brisbane/59/2007 (H1N1) (lot 58550257) that has been inactivated with beta-propiolactone (BPL), frozen as bulk, thawed, diluted 1:500 and dispensed 13JAN2022 to produce lot 70049760.

Lot: 70049760

Manufacturing Date: 23JUN2010

TEST	SPECIFICATIONS	RESULTS
Pre-Inactivation Titer by CEID₅₀ Assay in Embryonated Chicken Eggs¹ (2 days at 35°C with humidity)	Report results	1.8 × 10 ¹⁰ CEID ₅₀ /mL
Innocuity Test (Screening for Viral Inactivation in Eggs)^{2,3} NR-19322, Influenza A Virus, A/Brisbane/59/2007 (H1N1), BPL-inactivated ⁴ 1 st round of amplification (1:10) 2 nd round of amplification (neat) 3 rd round of amplification (neat) NR-12282, Influenza A Virus, A/Brisbane/59/2007 (H1N1), 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
Bulk Post-Inactivation Mycoplasma Contamination³ 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
Functional Activity⁴ 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 Detected
Post-Inactivation Sterility (21-day incubation)⁴ Harpo's HTYE broth, 37°C and 26°C, aerobic ⁵ 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

¹The Tissue Culture Infectious Dose 50% (TCID₅₀) endpoint is the 50% infectious endpoint in cell culture. The TCID₅₀ is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated, 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 TCID₅₀ provides a measure of the titer (or infectivity) of a virus preparation.

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.

³Test performed on bulk BPL-treated virus prior to dilution and vialing.

⁴Test performed on BPL-treated virus after dilution and vialing.

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

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