

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 70013122.

Lot: 70013513

Manufacturing Date: 10JUL2018

TEST	SPECIFICATIONS	RESULTS
Concentration¹	Report results	3.0 × 10 ⁸ CEID ₅₀ equivalents per mL
Innocuity Test (Screening for Viral Inactivation in Eggs)^{2,3} NR-19325, Influenza A Virus, A/Puerto Rico/8/1934, BPL-inactivated 1 st round of amplification 2 nd round of amplification NR-348, Influenza A Virus, A/Puerto Rico/8/1934 Positive Control 1 st round of amplification 2 nd round of amplification	No HA activity detected No HA activity detected HA activity detected HA activity detected	No HA activity detected No HA activity detected HA activity detected HA activity detected
Functional Activity RNA Detection by PCR of extracted test article nucleic acid ⁴ 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 Antigenicity using rapid influenza test ⁵ 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 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 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
Mycoplasma Contamination DNA detection by PCR of extracted test article nucleic acid	None detected	None detected

¹Concentration in CEID₅₀ equivalents per ml was calculated based on the titer of the virus before inactivation by BPL treatment.

²9- to 11-day old embryonated chicken eggs were inoculated with 0.2 mL of the indicated test sample and incubated at 35°C in an aerobic atmosphere 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 in an aerobic atmosphere for 2 days. Allantoic fluid from the second round of amplification was tested for HA activity.

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

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

⁵Using Remel Xpect™ Flu A&B kit (Catalog number R24600)

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

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10 DEC 2018

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