

Certificate of Analysis for NR-19268

Specific Pathogen-Free Chicken Embryo Allantoic Fluid, BPL-Treated

Catalog No. NR-19268

Product Description: NR-19268 is a preparation of allantoic fluid harvested from specific pathogen-free chicken (SPF) embryos and treated with beta-propiolactone (BPL).

Lot: 59284199 Manufacturing Date: 08JUN2010

TEST	SPECIFICATIONS	RESULTS
Functional Activity		
RNA detection by PCR of extracted Test Article nucleic acid		
Influenza A virus primer and probe set	None detected	None detected
Influenza H1 primer and probe set	None detected	None detected
Influenza H3 primer and probe set	None detected	None detected
Influenza H5a primer and probe set	None detected	None detected
Influenza H5b primer and probe set	None detected	None detected
Influenza B virus primer and probe set	None detected	None detected
Antigenicity using BD™ Directigen™ EZ Flu A+B (Cat. No. 256050) ³		
Influenza A	Report results	Non-reactive
Influenza B	Report results	Non-reactive
Sterility (21-day incubation)		
Harpo's HTYE broth⁴, 37°C and 26°C, aerobic	No growth detected	No growth detected
Trypticase soy broth, 37°C and 26°C, aerobic	No growth detected	No growth detected
Sabouraud broth, 37°C and 26°C, aerobic	No growth detected	No growth detected
Sheep blood agar, 37°C, aerobic	No growth detected	No growth detected
Sheep blood agar, 37°C, anaerobic	No growth detected	No growth detected
Thioglycollate broth, 37°C, anaerobic	No growth detected	No growth detected
DMEM with 10% FBS, 37°C and 5% CO ₂	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 amplification was tested for HA activity.

Date: 25 JAN 2011 Signature:

Title: Technical Manager, BEI Authentication or designee

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²The inoculum for the Positive Control (NR-12283) was 5.6 x 10⁶ CEID₅₀ per egg.

³Bulk BPL-treated allantoic fluid tested prior to vialing.

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