

Certificate of Analysis for NR-12280

Influenza B Virus, B/Malaysia/2506/04

Catalog No. NR-12280

This reagent is the property of the U.S. Government.

Product Description: Pooled allantoic fluid from specific-pathogen free (SPF) embryonated chicken eggs¹ infected with influenza B virus, B/Malaysia/2506/04.

Lot^{2,3}: 58550039 Manufacturing Date: 13MAR2009

TEST	SPECIFICATIONS	RESULTS
Identification by Infectivity Using Embryonated Chicken Eggs ¹ Hemagglutination activity using allantoic fluid from infected eggs and 0.5% chicken red blood cells	Positive	Positive
Sequencing of Species-Specific Region (~ 900 nucleotides)	Influenza B virus	Influenza B virus
Identification by Directigen EZ Flu A+B ⁴	Influenza B virus	Influenza B virus
Titer by CEID ₅₀ Assay ^{5,6} in Embryonated Chicken Eggs ¹	Report results	2.8 X 10 ⁸ CEID ₅₀ /mL
Sterility (BacT/ALERT® 3D Microbial Detection System) 14-day incubation of NR-12280: i NST culture bottle, 32°C, anaerobic i AST culture bottle, 32°C, aerobic	No growth No growth	No growth No growth
Mycoplasma Contamination 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

¹10 to 11-day-old SPF Fertile Chicken Eggs acquired from B&E Eggs, York Springs, Pennsylvania

Date: 29 SEP 2009 **Signature:** Signature on File

Title: Technical Manager, BEI Authentication or designee

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²Source virus for this lot was prepared in embryonated chicken eggs and provided by the NIH Biodefense and Emerging Infections Research Resources Repository, NIAID, NIH. Influenza B virus, B/Malaysia/2506/04 was isolated on June 12, 2004 from a human nasal swab in Malaysia. Following isolation this strain was passaged in eggs at the CDC followed by two egg passages at Baylor College of Medicine prior to deposition.

³Grown in the allantoic cavity of embryonated chicken eggs¹ for 48 hours at 33°C in a humidified chamber

⁴Using Directigen™ EZ Flu A+B Kit (BD 256050) for 48 hours at 33°C in ambient air

⁵The Chicken Embryo Infectious Dose 50% (CEID₅₀) is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the inoculated embryonated chicken eggs, 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 CEID₅₀ provides a measure of the infectious titer (or infectivity) of a virus preparation.

⁶² days at 33°C in ambient air