

## Certificate of Analysis for NR-44004

## Influenza A Virus, A/California/07/2009 (HA, NA) x A/Puerto Rico/8/1934 (H1N1)pdm09, Reassortant NYMC X-181

Catalog No. NR-44004

**Product Description:** Pooled allantoic fluid from specific pathogen free (SPF) embryonated chicken eggs<sup>1</sup> infected with reassortant influenza A virus, A/California/07/2009 (HA, NA) x A/Puerto Rico/8/1934 (H1N1)pdm09

Lot<sup>2</sup>: 61968408 Manufacturing Date: 21AUG2013

TEST	SPECIFICATIONS	RESULTS
Identification by Infectivity Using Embryonated Chicken Eggs <sup>1</sup> Hemagglutination activity using allantoic fluid from infected eggs and 0.5% chicken red blood cells	Positive	Positive
Sequencing of Hemagglutinin, Matrix, and Neuraminidase Coding Regions		
Hemagglutinin (411 nucleotides)	Consistent with NYMC X-181 (H1N1)pdm09	99% identity with NYMC X-181 (H1N1)pdm09 (GenBank: CY121688)
Matrix (913 nucleotides)	Consistent with NYMC X-181 (H1N1)pdm09	100% identity with NYMC X-181 (H1N1)pdm09 (GenBank: CY121689)
Neuraminidase (370 nucleotides)	Consistent with NYMC X-181 (H1N1)pdm09	99% identity with NYMC X-181 (H1N1)pdm09 (GenBank: CY121690)
Titer by CEID <sub>50</sub> Assay <sup>3,4</sup> in Embryonated Chicken Eggs <sup>1</sup>	Report results	2.8 × 10 <sup>9</sup> CEID <sub>50</sub> per mL
Sterility (21-day incubation)		
Harpo's HTYE broth⁵, 37°C and 26°C, aerobic	No growth	No growth
Trypticase soy broth, 37°C and 26°C, aerobic	No growth	No growth
Sabouraud broth, 37°C and 26°C, aerobic	No growth	No growth
Blood agar, 37°C, aerobic	No growth	No growth
Blood agar, 37°C, anaerobic	No growth	No growth
Thioglycollate broth, 37°C, anaerobic DMEM with 10% FBS, 37°C and 5% CO <sub>2</sub>	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

<sup>&</sup>lt;sup>1</sup>9- to 10-day-old SPF Embryonated Chicken Eggs acquired from B&E Eggs, York Springs, Pennsylvania <sup>2</sup>Grown in the allantoic cavity of embryonated chicken eggs<sup>1</sup> for 2 days at 35°C in a humidified chamber

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<sup>&</sup>lt;sup>3</sup>The Chicken Embryo Infectious Dose 50% (CEID<sub>50</sub>) 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% (LD<sub>50</sub>) is expected to kill half of the animals exposed. A reciprocal of the dilution required to yield the CEID<sub>50</sub> provides a measure of the infectious titer (or infectivity) of a virus preparation.

<sup>&</sup>lt;sup>4</sup>2 days at 35°C in a humidified chamber

<sup>&</sup>lt;sup>5</sup>Atlas, Ronald M. <u>Handbook of Microbiological Media</u>. 3rd ed. Ed. Lawrence C. Parks. Boca Raton: CRC Press, 2004, p. 798.



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Date: 08 JAN 2014 Signature: Michael Q. Gypthe

Title: Technical Manager, BEI Authentication or designee

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