

Certificate of Analysis for NR-44233

Human Respiratory Syncytial Virus, A1998/3-2, Purified from HEp-2 Cells

Catalog No. NR-44233

Product Description:

Human respiratory syncytial virus (RSV), A1998/3-2 was isolated from a nasal wash from an infant with RSV bronchiolitis in Nashville, Tennessee, USA, on March 2, 1998. NR-44233 lot 70059817 was produced by infecting human epithelial carcinoma cells (HEp-2; ATCC® CCL-23™) and incubating in Eagle's Minimum Essential Medium (ATCC® 30-2003™) supplemented with 2% fetal bovine serum (ATCC® 30-2020™) for 7 days at 37°C with 5% CO₂. The virus was purified from clarified supernatant by high speed centrifugation.

Lot: 70059817 Manufacturing Date: 12APR2023

TEST	SPECIFICATIONS	RESULTS
Identification by Infectivity in HEp-2 Cells	Syncytia, cell rounding and detachment	Syncytia, cell rounding and detachment
Sequencing of Species-Specific Region (~ 830 nucleotides)	≥ 98% identity with RSV, A1998/3-2 (GenBank: JX069801)	100% identity with RSV, A1998/3-2 (GenBank: JX069801)
Titer by TCID ₅₀ Assay in HEp-2 Cells by Cytopathic Effect ¹ (8 days at 37°C with 5% CO ₂)	Report results	2.8 × 10 ⁶ TCID ₅₀ /mL
SDS-PAGE Analysis	Report results	Three bands of ~90 kDa, ~50 kDa and ~44 kDa
Sterility (21-day incubation)		
Harpo's HTYE broth, 37°C and 26°C, aerobic ²	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
Sheep blood agar, 37°C, aerobic	No growth	No growth
Sheep blood agar, 37°C, anaerobic	No growth	No growth
Thioglycollate broth, 37°C, anaerobic	No growth	No growth
DMEM with 10% FBS, 37°C, aerobic	No growth	No growth
Mycoplasma Contamination		
Agar and broth culture (14-day incubation at 37°C)	None detected	None detected
DNA detection by PCR of extracted Test Article nucleic acid	None detected	None detected

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. ²Atlas, Ronald M. <u>Handbook of Microbiological Media</u>. 3rd ed. Ed. Lawrence C. Parks. Boca Raton: CRC Press, 2004, p. 798.

/Sonia Bjorum Brower/ Sonia Bjorum Brower

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Technical Manager or designee, ATCC Federal Solutions

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