

Certificate of Analysis for NR-52287

SARS-Related Coronavirus 2, Isolate USA-WA1/2020, Gamma-Irradiated

Catalog No. NR-52287

Product Description:

NR-52287 lot 70035888 consists of a crude preparation of cell lysate and supernatant from *Cercopithecus aethiops* kidney epithelial cells (Vero E6; ATCC[®] CRL-1586™) infected with severe acute respiratory syndrome-related coronavirus 2 (SARS-CoV-2), isolate USA-WA1/2020 (NRC-52281 lot 70035365) that was gamma-irradiated (5 × 10⁶ RADs) on dry ice.

Lot: 70035888 Manufacturing Date: 27MAY2020

TEST	SPECIFICATIONS	RESULTS
Pre-Inactivation Titer by TCID ₅₀ Assay in Vero E6 Cells ¹ (5 days at 37°C and 5% CO ₂)	Report results	2.8 × 10 ⁶ TCID ₅₀ per mL
Pre-Inactivation 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
Pre-Inactivation 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
Genome Copy Number Using BioRad QX200 Droplet Digital PCR (ddPCR™) System³ (Post vial; 15 replicates)	Report results	1.75 × 10 ⁹ genome equivalents/mL
Endotoxin Content (<i>Limulus</i> Amoebocyte Lysate Assay) ⁴	Report results	≤ 0.02 EU per mL
Virus Inactivation (Post-Inactivation) 10% of total bulk irradiated preparation was plated on Vero E6 cells for 14 days at 37°C and 5% CO ₂ for two passages and evaluated for cytopathic effect and expression of viral antigen by indirect immunofluorescence assay ⁵	No viable virus detected	No viable virus 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.

/Heather Couch/

Heather Couch 23 JUL 2020

Program Manager or designee, ATCC Federal Solutions

ATCC®, on behalf of BEI Resources, hereby represents and warrants that the material provided under this certificate has been subjected to the tests and procedures specified and that the results described, along with any other data provided in this certificate, are true and accurate to the best of ATCC®'s knowledge.

ATCC® is a trademark of the American Type Culture Collection.

You are authorized to use this product for research use only. It is not intended for human use.

BEI Resources www.beiresources.org E-mail: contact@beiresources.org

Tel: 800-359-7370 Fax: 703-365-2898

²Atlas, Ronald M. <u>Handbook of Microbiological Media</u>. 3rd ed. Ed. Lawrence C. Parks. Boca Raton: CRC Press, 2004, p. 798. ³The GE value reported is obtained using Qiagen RNA extraction kit (Cat 52904).

⁴Tested using Lonza Pyrogent™ (Cat N294-03)

⁵Performed at University of Texas Medical Branch, Galveston, Texas, USA