

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

Catalog No. NR-52287

Product Description:

NR-52287 lot 70039067 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 70039066) that was gamma-irradiated (5×10^6 RADs) on dry ice, followed by sonication to clarify the supernatant.

Lot: 70039067

Manufacturing Date: 30SEP2020

| TEST | SPECIFICATIONS | RESULTS |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| Pre-Inactivation Titer by TCID₅₀ Assay in Vero E6 Cells¹ (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 Trypticase soy broth, 37°C and 26°C, aerobic Sabouraud broth, 37°C and 26°C, aerobic Sheep blood agar, 37°C, aerobic Sheep blood agar, 37°C, anaerobic Thioglycollate broth, 37°C, anaerobic DMEM with 10% FBS, 37°C, aerobic | No growth No growth No growth No growth No growth No growth No growth | No growth No growth No growth No growth No growth No growth No growth |
| Pre-Inactivation 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 |
| Post Vial Genome Copy Number Using BioRad QX200 Droplet Digital PCR (ddPCR™) System³ | Report results | 1.57×10^9 genome equivalents/mL ⁴ |
| 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.

²Atlas, Ronald M. *Handbook of Microbiological Media*. 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).

⁴Two vials of NR-52287 lot 70039067 were used for RNA extraction. Average of the results obtained from nine replicates from each vial is reported.

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

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