

# **Certificate of Analysis for NR-56129**

# SARS-Related Coronavirus 2, Isolate hCoV-19/USA/MD-HP05285/2021 (Lineage B.1.617.2; Delta Variant), Gamma-Irradiated

## Catalog No. NR-56129

### **Product Description:**

NR-56129 is a gamma-irradiated preparation of severe acute respiratory syndrome-related coronavirus 2 (SARS-CoV-2), isolate hCoV-19/USA/MD-HP05285/2021. NR-56129 was gamma-irradiated (5 × 10<sup>6</sup> RADs) on dry ice, followed by sonication to clarify the supernatant prior to vialing.

The starting material (BEI Resources lot 70047502) was produced by infecting *Homo sapiens* lung adenocarcinoma epithelial cells (Calu-3) in Eagle's Minimum Essential Medium (ATCC® 30-2003<sup>™</sup>) supplemented with 2% fetal bovine serum (ATCC® 30-2020<sup>™</sup>) for 3 days at 37°C with 5% CO<sub>2</sub>. Titer of spin clarified lot 70047502 was 4.4 × 10<sup>6</sup> TCID<sub>50</sub> per mL by TCID<sub>50</sub> assay in Calu-3 cells, determined by cytopathic effect in 7 days at 37°C with 5% CO<sub>2</sub>, and sterility of the preparation was confirmed.

Lot: 70048070 Manufacturing Date: 08OCT2021

TEST	SPECIFICATIONS	RESULTS
Genome Copy Number Using BioRad QX200 Droplet Digital PCR (ddPCR™) System¹	Report results	1.13 × 10 <sup>9</sup> genome copies per mL <sup>2</sup>
Virus Inactivation  10% of total bulk gamma-irradiated preparation inoculated on Vero E6 cells and evaluated for cytopathic effect and expression of viral antigen by indirect immunofluorescence assay <sup>3,4</sup>	No viable virus detected	No viable virus detected

<sup>&</sup>lt;sup>1</sup>The genome copy number reported is obtained using Qiagen RNA extraction kit (Cat 52906).

#### /Heather Couch/

Heather Couch 01 FEB 2022

Program Manager or designee, ATCC Federal Solutions

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BEI Resources www.beiresources.org E-mail: contact@beiresources.org
Tel: 800-359-7370

Fax: 703-365-2898

<sup>&</sup>lt;sup>2</sup>The results obtained from nine replicates is reported.

<sup>&</sup>lt;sup>3</sup>The gamma-irradiated virus preparation was plated on Vero E6 cells and incubated for 14 days at 37°C and 5% CO<sub>2</sub>; cell lysate and supernatant from these cultures were blind passaged on fresh monolayers of Vero E6 cells and again incubated for 14 days at 37°C and 5% CO<sub>2</sub>.

Indirect immunofluorescence assay performed at University of Texas Medical Branch, Galveston, Texas, USA