

Certificate of Analysis for NR-56128

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

Catalog No. NR-56128

Product Description:

NR-56128 is a preparation of SARS-Related Coronavirus 2 (SARS-CoV-2), isolate hCoV-19/USA/MD-HP05285/2021 that has been inactivated by heating to 65°C for 30 minutes, followed by 10-fold dilution prior to vialing.

The starting material (lot 70046638) was produced by infecting *Homo sapiens* lung adenocarcinoma epithelial cells (Calu-3; ATCC® HTB-55™) with SARS-CoV-2, isolate hCoV-19/USA/MD-HP05285/2021 in Eagle's Minimum Essential Medium (ATCC® 30-2003™) supplemented with 2% fetal bovine serum (ATCC® 30-2020™) for 3 days at 37°C with 5% CO₂. The titer of spin clarified source material prior to dilution was 1.1 × 10⁶ TCID₅₀ per mL by TCID₅₀ assay in Calu-3 cells, determined by cytopathic effect in 5 days at 37°C with 5% CO₂, and sterility of the preparation was confirmed.¹

Lot: 70048021 Manufacturing Date: 23SEP2021

TEST	SPECIFICATIONS	RESULTS
Genome Copy Number Using BioRad QX200 Droplet Digital PCR (ddPCR™) System² (27 replicates)	Report results	8.62 × 10 ⁸ genome equivalents per mL
Virus Inactivation 10% of total bulk heat-treated preparation inoculated on Vero E6-TMPRSS2-T2A-ACE2 cells and evaluated for cytopathic effect and presence of viral RNA by qRT-PCR ³	No viable virus detected	No viable virus detected

¹The Tissue Culture Infectious Dose 50% (TCID₅₀) 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.

²The genome copy number reported is obtained using Qiagen RNA extraction kit (Cat 52906).

/Heather Couch/ Heather Couch

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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.

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³The inactivated virus preparation was plated on Vero E6-TMPRSS2-T2A-ACE2 cells and incubated for 14 days at 37°C and 5% CO₂; cell lysate and supernatant from these cultures were blind passaged on fresh monolayers of Vero E6-TMPRSS2-T2A-ACE2 cells and again incubated for 14 days at 37°C and 5% CO₂. Samples from both passages were tested by qPCR at the end of day 14 of the passages.