

SARS-Related Coronavirus 2, Isolate USA/MD-HP01542/2021 (Lineage B.1.351), Heat Inactivated

Catalog No. NR-55350

Product Description:

NR-55350 is a preparation of SARS-Related Coronavirus 2 (SARS-CoV-2), isolate USA/MD-HP01542/2021 that has been inactivated by heating to 65°C for 30 minutes, followed by 5-fold dilution prior to vialing.

The starting material (lot 70043444) was produced by infecting *Homo sapiens* lung adenocarcinoma epithelial cells (Calu-3; ATCC® HTB-55™) 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. Titer of spin clarified source material was 1.1 × 10⁵ TCID₅₀ per mL by TCID₅₀ assay in Calu-3 cells, determined by cytopathic effect in 8 days at 37°C with 5% CO₂, and sterility of the preparation was confirmed.¹

Lot: 70045608

Manufacturing Date: 01JUL2021

TEST	SPECIFICATIONS	RESULTS
Genome Copy Number Using BioRad QX200 Droplet Digital PCR (ddPCR™) System² (17 replicates)	Report results	6.08 × 10 ⁷ genome equivalents per mL
Virus Inactivation 10% of total bulk heat-treated preparation inoculated on Vero E6 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).

³The inactivated virus preparation was plated on Calu-3 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 Calu-3 cells and again incubated for 14 days at 37°C and 5% CO₂. Samples from both passages were also tested by qPCR at the end of day 14 of the passages.

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29 SEP 2021

Program Manager or designee, ATCC Federal Solutions

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