

**Monkeypox Virus, hMPXV/USA/MA001/2022 (Lineage B.1, Clade IIb), Heat Inactivated**

**Catalog No. NR-58711**

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**Product Description:**

NR-58711 is a preparation of monkeypox virus, hMPXV/USA/MA001/2022 that has been inactivated by heating to 65°C for 30 minutes and diluted prior to vialing.

The starting material (lot 70056098) was produced by infecting *Cercopithecus aethiops* kidney epithelial cells (BSC-40; ATCC® CRL-2761™) with depositor material (monkeypox virus, hMPXV/USA/MA001/2022) in Dulbecco's Modified Eagle Medium (ATCC® 30-2002™) supplemented with 2% fetal bovine serum (ATCC® 30-2020™) for 4 days at 37°C with 5% CO<sub>2</sub>. The titer of spin clarified source material prior to dilution was 8.9 × 10<sup>6</sup> TCID<sub>50</sub> per mL by TCID<sub>50</sub> assay in BSC-40 cells, determined by cytopathic effect in 7 days at 37°C with 5% CO<sub>2</sub>, and sterility of the preparation was confirmed.<sup>1</sup>

**Lot: 70056171**

**Manufacturing Date: 18OCT2022**

TEST	SPECIFICATIONS	RESULTS
<b>NDU Using BioRad QX200 Droplet Digital PCR (ddPCR™) System<sup>2,3</sup></b> (Post-vial; 16 replicates)	Report results	5.03 × 10 <sup>6</sup> NDU per mL
<b>Virus Inactivation</b> 10% of total bulk heat-treated preparation inoculated on BSC-40 cells and evaluated for cytopathic effect and presence of viral RNA by qRT-PCR <sup>4</sup>	No viable virus detected	No viable virus detected

<sup>1</sup>The Tissue Culture Infectious Dose 50% (TCID<sub>50</sub>) is the 50% infectious endpoint in cell culture. The TCID<sub>50</sub> 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% (LD<sub>50</sub>) is expected to kill half of the animals exposed. A reciprocal of the dilution required to yield the TCID<sub>50</sub> provides a measure of the titer (or infectivity) of a virus preparation.

<sup>2</sup>NDU: Nucleic Acid Amplification Test (NAAT)-Detectable Units.

<sup>3</sup>ddPCR values may differ depending on the efficiency of the extraction method used. Qiagen QIAamp Viral RNA Mini kit (Qiagen® 52906) was used for the extraction of lot 70053171.

<sup>4</sup>The inactivated virus preparation was plated on BSC-40 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 BSC-40 cells and again incubated for 14 days at 37°C and 5% CO<sub>2</sub>. Samples from both passages were tested by qPCR at the end of day 14 of the passages.

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