

Certificate of Analysis for NR-59451

Whole Cell Antigen, MPXV hMPXV/USA/MA001/2022, Clade II with Uninfected Control BSC-40 Cells, Gamma-Irradiated

Catalog No. NR-59451

This reagent is the property of the U.S. Government.

Product Description:

NR-59451 is a whole cell antigen kit with two components, NR-58721 and NR-58720 (Table 1), prepared following the same procedure. NR-58721 was prepared from pelleted uninfected *Chlorocebus* (previously *Cercopithecus*) *aethiops* kidney epithelial cells (BSC-40) and NR-58720 was prepared from BSC-40 cells infected with MPXV hMPXV/USA/MA001/2022, Clade II. Cell pellets were gamma-irradiated (5 × 10⁶ RADs) on dry ice, followed by sonication and centrifugation to clarify. The supernatant containing the irradiated antigen was aliquoted and vialed.

Table 1: MPXV Whole Cell Antigen Kit Components

| COMPONENT NUMBER | DESCRIPTION | LOT NUMBER | DATE OF MANUFACTURE |
|------------------|---|------------|---------------------|
| NR-58721 | Gamma-irradiated uninfected BSC-40 whole cell antigen control | 70055681 | 12SEP2022 |
| NR-58720 | Gamma-irradiated SARS-CoV-2, isolate MPXV hMPXV/USA/MA001/2022, Clade II whole cell antigen | 70055679 | 10AUG2022 |

Table 2: Gamma-Irradiated MPXV hMPXV/USA/MA001/2022, Clade II infected BSC-40 Cell Lysate (NR-58720)

| TEST | SPECIFICATIONS | RESULTS |
|--|--------------------------|--------------------------|
| Virus Inactivation | | |
| 10% of total bulk gamma-irradiated preparation inoculated on BSC-40 cells and evaluated for cytopathic effect and by qPCR. 1,2 | No viable virus detected | No viable virus detected |

¹ Inactivation testing performed at BEI Resources.

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²The gamma-irradiated virus preparation was plated on plated on BSC-40 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 BSC-40 cells and again incubated for 14 days at 37°C and 5% CO₂.