

NATtrol™ Mpx Virus External Run Control

PRODUCT DESCRIPTION:

NATtrol™ Mpx Virus External Run Control (NATMPXV-ERC) contains purified, intact viral particles that have been chemically modified to render them non-infectious and refrigerator stable. The control is supplied in a proprietary matrix.

INTENDED USE:

NATtrol™ Mpx virus external run control is designed to evaluate the performance of nucleic acid tests for determination of the presence of Mpx virus DNA. NATtrol™ Mpx virus external run control enables laboratories to monitor test variation, lot-to-lot test kit performance, operator variation, and can provide assistance in identifying random or systemic error.

MATERIALS SUPPLIED:

- Each control pack contains 6 x 0.5 mL vials.

WARNINGS AND PRECAUTIONS:

- NATtrol™ inactivation was carried out on the Mpx viral stock used to formulate the control. The inactivation was verified in a standard microbiological growth protocol.
- This product contains inactivated Mpx virus and materials of human and animal origin. Safe practices suggest that the controls be considered potentially infectious and to use Universal Precautions when handling.
- Refer to CDC guidelines and local regulations for handling and disposal.
- The matrix used in the manufacture of this product is treated with 0.09% sodium azide. It was manufactured from Human Serum Albumin that has been tested and found to be non-reactive at the donor level for HIV-1/HIV-2 Antibody, HBsAg and HCV Antibody by FDA licensed donor screening test methods. All materials are also tested for HIV-1 and HCV by FDA approved Nucleic Acid Test (NAT) methods.
- Heat inactivated Fetal Bovine Serum used in the manufacture of this product meets applicable USDA requirements for abattoir sourced animals, traceability, and country of origin. The materials were collected at USDA licensed establishments or legally imported from countries recognized by the USDA as negligible or controlled for risk for Bovine Spongiform Encephalopathy (BSE) and other exotic disease agents. Donor animals were inspected ante and postmortem at the abattoir as required by the USDA.
- Do not use past the expiration date on the label.
- To avoid cross-contamination, use separate pipette tips for all materials.

RECOMMENDED STORAGE:

- NATtrol™ Mpx Virus External Run Control should be stored at 2-8°C.

INSTRUCTIONS FOR USE:

- Mix tube vigorously for at least 5 secs.
- Process according to manufacturer's instructions for sample to result assays.
- Extract nucleic acid prior to use in downstream assays that are not sample to result.

LIMITATIONS:

- **FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.**
- Quality control materials should be used in accordance with local, state, federal, and accreditation requirements.
- This product is not intended to replace the manufacturer's controls provided with the assay.

NATtrol™ Mpox Virus External Run Control

EXPECTED RESULTS:

- The target concentration value provided in Table 1 is tested in ZeptoMetrix in-house real-time PCR assay.
- It is the responsibility of the end user to establish their own acceptance criteria for the control using their laboratory's procedures.








Table 1

Catalog Number	Isolate ¹	Target Concentration (copies/mL) ²
NATMPXV-ERC	USA/MA001/20221	15,000

¹This reagent was deposited by the Centers for Disease Control and Prevention and obtained through BEI Resources, NIAID, NIH: Monkeypox Virus, hMPXV/USA/MA001/2022 (Lineage B.1, Clade IIb), NR-58622.

²Based on in-house real time PCR assay targeting the E9L gene region.

Symbols used in the labeling of this product:

	Manufacturer		Temperature Limitation
	For Research Use Only		Expiration Date
	Catalog Number		Biological Risk
	Batch Code		