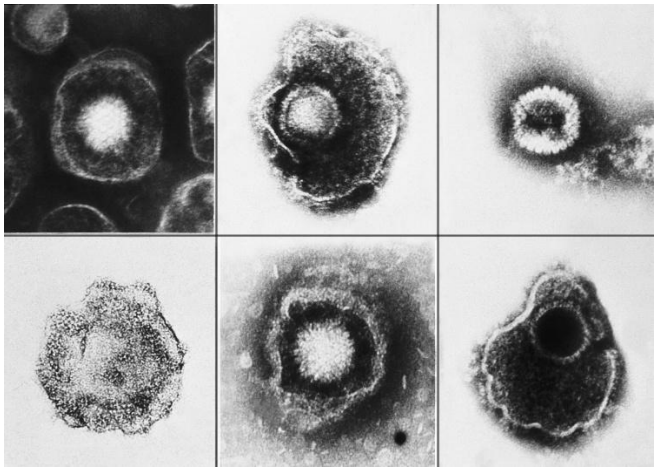
Herpes Simplex Virus Type 2 (HSV-2) Molecular Control



Product Name

Herpes Simplex Virus Type 2 (HSV-2) Molecular Control

Specification

500 µL / vial (liquid)

Appearance

Clear, colorless to slightly opalescent liquid

Storage Conditions

- **Unopened:** −20 °C ± 5 °C
- **After opening:** 2–8 °C

Description

The Herpes Simplex Virus Type 2 (HSV-2) Molecular Control is prepared from inactivated HSV-2 viral material.
It retains an intact viral genome and is designed to closely mimic clinical specimens. This control demonstrates excellent commutability with patient samples and is suitable for use with a wide range of HSV-2 nucleic acid amplification assays.

Intended Use

This product is a third-party, unassigned quality control material intended for:

- Monitoring assay performance
- Verifying analytical sensitivity
- Supporting routine quality assurance of HSV-2 molecular diagnostic tests

For in vitro diagnostic (IVD) use only.

Product Information

Analyte	Description	Assigned Value	Assignment Method
HSV-2 Molecular Control	HSV-2 DNA	≥ 5×10^4 copies/mL	Digital PCR

Shipping Conditions

Shipped on dry ice.

Stability

- **Shelf life:** 24 months from date of manufacture (unopened, at −20 °C)
- **After opening:** Stable for up to 4 weeks at 2-8 °C
- Avoid repeated freeze–thaw cycles

Compatible Instruments

- Real-time PCR systems
- Other nucleic acid amplification platforms validated for HSV-2 detection

Procedure

1. Allow the control to equilibrate to room temperature (15–30 °C) for 5–10 minutes before use.
2. Mix thoroughly by gentle vortexing and briefly centrifuge.
3. Process the control exactly as a clinical specimen, from nucleic acid extraction through amplification.
4. Do not dilute or aliquot the control.
5. Follow the minimum input volume specified by the extraction kit in use.
6. Use extracted nucleic acid immediately or store at −20 °C for up to 36 hours.
7. Perform amplification according to the instructions of the corresponding HSV-2 detection kit.
8. Use only DNase/RNase-free consumables.

Quality Control

It is recommended to include this control in:

- Each testing run, or
- At a frequency defined by the laboratory's quality management system

Laboratories should establish and maintain control charts to monitor assay performance and variability.

Warnings and Precautions

- Although inactivated, this product should be handled as potentially biohazardous
- Use by trained laboratory personnel only
- Follow standard biosafety and waste disposal procedures
- Do not use beyond the expiration date

Regulatory Status

- For In Vitro Diagnostic Use
- Not intended for therapeutic or clinical decision-making as a standalone result