

# INSTRUCTIONS FOR USE



## ■ Inactivated Helix Elite™ Molecular Standards (Inactivated Pellet)

### INTENDED USE

The Inactivated Helix Elite™ Molecular Standards are intended for use as non-viable, external, positive control materials to evaluate the performance of nucleic acid amplification testing (NAAT) procedures that detect the analytes in Annex 1. These products have no qualitative or quantitative assigned value. These control materials are nonautomated and not intended to be used for screening, monitoring, or diagnosis. These controls are not intended for any specific patient population or specimen.

### SUMMARY AND PRINCIPLES

The Inactivated Helix Elite™ Molecular Standards can be used to monitor the extraction, amplification and detection process of molecular testing assays that include the analytes in Annex 1. Routine use of quality controls monitor test variation, lot-to-lot test kit performance, operator performance, and aid in identifying random or systemic error.

### COMPOSITION


The Inactivated Helix Elite™ Molecular Standards consist of 5 individually packaged lyophilized pellets. The analytes in Annex 1 have been inactivated using irradiation and thermal treatments.

The Inactivated Helix Elite™ Molecular Standards are lyophilized in a PCR compatible matrix. The organisms are prepared in a buffered solution with materials of plant and animal origin, preservatives, and stabilizers. The solution is lyophilized into a ready-to-use pellet.

### WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic use only.
- For professional use only. To be used by personnel trained in the use of the assay.
- The inactivated lyophilized pellets are single-use only. Once hydrated, do not freeze for reuse.
- Do not open foil pouch until ready to use.
- Although this product has been inactivated, there is no known test or inactivation method that can assure that it will not transmit infection. This product must be treated as a potential biohazard. Wear appropriate personal protective equipment. Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are handled. Disinfect any spills, and dispose of all materials in accordance with national and local regulations.
- Refer to the Safety Data Sheet (SDS) for more detailed information. The SDS can be located on the Microbiologics website at [www.microbiologics.com](http://www.microbiologics.com) or by contacting Customer Service at [info@microbiologics.com](mailto:info@microbiologics.com).
- These products do not contain any hazardous substances listed in 1272/2008/EC.
- Report any serious incident that has occurred in relation to the device to Microbiologics and the local regulatory officials in which the user and/or the patient is established.

### STORAGE AND EXPIRATION

 25°C Store the Inactivated Helix Elite™ Molecular Standards at 2°C-25°C in the original packaging up to the indicated expiration date. After opening the foil pouch, rehydrate and use immediately. In-use stability of the rehydrated pellet at room temperature (25°C) is 6 hours.



The Inactivated Helix Elite™ Molecular Standards should not be used if:

- Stored improperly
- There is evidence of excessive exposure to heat or moisture
- The expiration date has passed
- Packaging is damaged

## MATERIALS REQUIRED BUT NOT PROVIDED

- Nucleic acid extraction kit and assay
- Instrumentation for detection
- Rehydration fluid/buffer such as nuclease-free water, phosphate-buffered saline (PBS), or transport medium as required by assay to be performed
- Pipettors capable of delivering 0.5-1000 µl volumes
- Nuclease-free aerosol barrier pipette tips
- Vortex
- Microcentrifuge (optional)

## INSTRUCTIONS FOR USE

1. Read package insert, instructions for use or lab protocol for the applicable assay. Some instruments and assays are equipped with special QC settings. In these instances, it may be necessary to use the special setting when using QC sets and panels.
2. Tear open pouch at notch. Remove vial from pouch and ensure the pellet is at the bottom of the vial before opening.
3. Hydrate the lyophilized pellet into a vial/tube of hydrating fluid/buffer recommended by the assay manufacturer.
  - a. If not using a provided hydration fluid/buffer from the assay manufacturer, please refer to Table 1 below for sample volume and known extrinsic factors and interfering substances.
4. Recap the vial/tube and vortex for 10 seconds at full speed to mix.
5. If a centrifuge is not available, tap the capped vial/tube on a rigid surface to collect material at the bottom of the vial/tube.
  - a. Alternatively, centrifuge briefly to collect any droplets clinging to the cap or upper walls of the vial/tube.
6. Use the appropriate volume for the assay being performed and follow laboratory protocols or manufacturer instructions for processing a sample.
7. Note: Dilutions may be performed and used immediately. Storage of diluted material for future use is not recommended

Table 1: Sample Volume

Hydration Fluid/Buffer	Minimum Hydration Volume	Mix Format/Time	Known Extrinsic Factors and Interfering Substances
Nuclease-Free Water	100 µl	Vortex for 10 seconds	N/A
Phosphate-Buffered Saline (PBS)	100 µl	Vortex for 10 seconds	N/A
Transport Medium	100 µl	Vortex for 10 seconds	N/A

\*Other volumes may be appropriate for the chosen assay

























## LIMITATIONS

- These products are unassayed control materials. They may not be suitable for use with all kits and procedures as not all instruments and assays are compatible with multi-target controls. Customer is responsible for verifying the performance of this product with their chosen instrumentation and assay(s). As a third-party control manufacturer, Microbiologics' provides quality controls that deliver an independent, unbiased assessment of performance with any instrument or method. While not intended to replace control materials provided by the assay/instrument supplier, third-party control materials should be considered.
- Target concentrations of each analyte are specific to Microbiologics' assay method and procedures. These organisms are intact, non-viable, and may be used with any PCR-based test or assay. Microbiologics guarantees each nucleic acid is present and can be amplified but does not guarantee specific analyte concentrations. Each laboratory should establish its own range of acceptable values on their assay system per their internal quality assurance procedure/program. Nucleic acid reactivity, which may vary over time, is dependent on a laboratory's instrumentation, assay method, procedures, calibration, or technician. Microbiologics' molecular controls are not calibrators and should not be used for assay calibration or as an absolute reference material.

## MICROBIOLOGICAL STATE

These products were prepared using suitable inactivation methods. While they have been tested for innocuity, universal laboratory precautions are recommended, and material should be treated as though it was a viable specimen.

## KEY OF SYMBOLS

	Authorized Representative in the European Community / European Union		In vitro diagnostic medical device
	Batch code (Lot)		Manufacturer
	Biological risks		Negative control
	Catalog number		Positive control
	Caution		Quantity
	CE mark		Swiss Authorized Representative
	Consult instructions for use or consult electronic instructions for use		Telephone number
	Contains sufficient for <n> tests		Temperature limit
	Device for near-patient testing		UK Conformity Assessed mark
	Do not re-use		UK Responsible Person
	Do not use if package is damaged and consult instructions for use		Use-by-date
	Health hazard		Water; Fluid

*Please refer to product labels for applicable symbols.*

## NOTICE TO PURCHASERS

The purchase of these products allows the purchaser to use it for Research and Quality Control. No general patents or other license of any kind other than this specific right of use from purchase is granted hereby. No other rights are conveyed expressly, by implication or by estoppel to any other patents. Furthermore, no rights for resale are conferred with the purchase of these products.

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## WEBSITE

Visit our website, [www.microbiologics.com](http://www.microbiologics.com), for current technical information and product availability.

## ASSISTANCE



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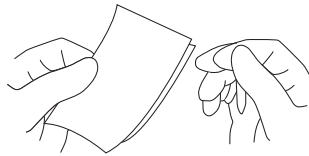
Freiburgstrasse 3, 3010  
Bern, Switzerland

Additional copies of this product insert may be obtained at [www.microbiologics.com](http://www.microbiologics.com) or by emailing [info@microbiologics.com](mailto:info@microbiologics.com)

## ILLUSTRATED INSTRUCTIONS

1

Read package insert, instructions for use or lab protocol for the applicable assay. Some instruments and assays are equipped with special QC settings. In these instances, it may be necessary to use the special setting when using QC sets and panels.



2

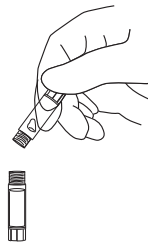


Tear open pouch at notch. Remove vial from pouch and ensure the pellet is at the bottom of the vial before opening.

3

Hydrate the lyophilized pellet into a vial of hydrating fluid/buffer recommended by the assay manufacturer.

If not using a provided hydration fluid/buffer from the assay manufacturer, please refer to Table 1 for sample volume and known extrinsic factors and interfering substances.

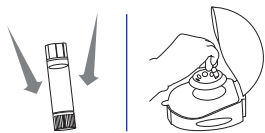


4



Recap the vial/tube and vortex for 10 seconds at full speed to mix.

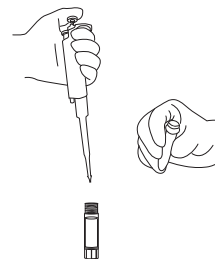
5



If a centrifuge is not available, tap the capped vial/tube on a rigid surface to collect material at the bottom of the vial/tube. Alternatively, centrifuge briefly to collect any droplets clinging to the cap or upper walls of the vial/tube.

6

Use the appropriate volume for the assay being performed and follow laboratory protocols or manufacturer instructions for processing a sample.



7

Note: Dilutions may be performed and used immediately. Storage of diluted material for future use is not recommended.

## REVISION HISTORY ---

Publication History		
Revision	Date	Description of Change
A	2023-06-13	Initial release to IVDR

## ANNEX 1 SUMMARY OF ANALYTES ---

Item #	Item Name	Analytes	Inactivation Method
HE0034N	Inactivated Chlamydia pneumoniae	<i>Chlamydia pneumoniae</i> , Strain CWL-029	Irradiation
HE0035N	Inactivated Chlamydia trachomatis	<i>Chlamydia trachomatis</i> , Strain LGV-2-434	Irradiation
HE0039N	Inactivated Cytomegalovirus Low Control	Cytomegalovirus, Strain AD-169	Irradiation
HE0040N	Inactivated Cytomegalovirus High Control	Cytomegalovirus, Strain AD-169	Irradiation
HE0045N	Inactivated Chlamydia trachomatis/ Neisseria gonorrhoeae (CT/NG)	<i>Chlamydia trachomatis</i> , Strain LGV-2-434 <i>Neisseria gonorrhoeae</i>	Irradiation, Thermal

