

INSTRUCTIONS FOR USE



■ Helix Elite™ Molecular Standards

INTENDED USE

Inactivated **Helix Elite™ Molecular Standards** are unassayed positive controls in molecular testing.

SUMMARY AND EXPLANATION

Molecular tests offer rapid and accurate results regarding the presence and quantity of an organism. Proper interpretation of a molecular test requires the use of a positive control. Inactivated **Helix Elite™ Molecular Standards** are easy-to-use process controls that can be used to monitor the extraction, amplification and detection of new molecular assays or instruments. These independent controls may also be used in evaluation of laboratory proficiency and training, or determination of the lot-to-lot consistency of assay consumables as directed by various regulatory requirements and standards.

PRINCIPLE

Inactivated **Helix Elite™ Molecular Standards** are intact pathogens inactivated by chemical, radiological, or heat treatments. Target pathogens are lyophilized in a PCR compatible matrix, and stable at 2°C-25°C through the expiration date. Each lyophilized pellet is packaged in a single-use foil pouch. Users should follow assay manufacturers, or laboratory procedures for processing positive controls.

COMPOSITION

The lyophilized preparation consists of:

- Inactivated pathogen
- Excipients including skim milk (Bovine –USA origin), gelatin (Porcine - USA or Canada origin) carbohydrate, and ascorbic acid.

WARNINGS AND PRECAUTIONS

- Do not open foil pouch until ready to rehydrate and use.
- Material has been inactivated, but should be handled and disposed of as infectious material.
- Wear proper personal protective equipment.
- Refer to the Safety Data Sheet (SDS) for more detailed information. The SDS can be located on the Microbiologics website at www.microbiologics.com under document library or by contacting Technical Support at 320.229.7045 or U.S. Toll Free 1.866.286.6691.
- These products do not contain any hazardous substances listed in 67/548/EEC or listed in 1272/2008/EC.
- These products are not made with natural rubber latex.



MATERIALS REQUIRED BUT NOT PROVIDED

- Nucleic acid extraction kit and assay/instrumentation for detection
- Rehydration buffer such as PBS or viral transport medium
- Pipettors capable of handling 0.5-1000 µl volumes
- Nuclease-free aerosol barrier pipette tips
- Vortex mixer
- Microcentrifuge with rotor

INSTRUCTIONS FOR USE

1. Open the foil pouch and ensure that the pellet is at the bottom of the vial before opening.
2. Rehydrate the lyophilized pellet with the appropriate buffer. A minimum volume of 100 µl is recommended.
3. Vortex briefly to mix. Centrifuge to collect the rehydrated, inactivated target material at the bottom of the tube.
4. Use the appropriate volume for the assay being performed and follow laboratory protocols or manufacturer instructions for processing a sample. **Note:** Each pellet is intended as a single use test. Dilutions may be performed and used immediately. Storage of the rehydrated or diluted material is not recommended.

STORAGE AND EXPIRATION

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, use the pellet immediately.

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

LIMITATIONS

This product may not be suitable for use with all kits and procedures. Only primers and probes that hybridize to sequences of the extracted nucleic acids of the organism should be expected to yield a positive reaction.

MICROBIOLOGICAL STATE

This product was prepared using suitable inactivation methods. While the product has been tested for innocuity, universal laboratory precautions are recommended and material should be treated as though it was a viable specimen.

KEY OF SYMBOLS



Batch Code (Lot)



Catalog Number



Counting



In Vitro Diagnostic Medical Device



Manufacturer



Temperature Limitation



Use By



Refer to Instructions for Use

PRODUCT WARRANTY ---

- These products are warranted to meet the specifications and performance printed and illustrated in product inserts, instructions, and supportive literature.
- The warranty, expressed or implied, is limited when:
 - The procedures employed in the laboratory are contrary to printed and illustrated directions and instructions.
 - The products are employed for applications other than the intended use cited in product inserts, instructions, and supportive literature.

NOTICE TO PURCHASERS ---

The purchase of this product 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 this product.

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WEBSITE ---

Visit our website, www.microbiologics.com, for current technical information and product availability.

ACKNOWLEDGEMENTS ---



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ILLUSTRATED INSTRUCTIONS

1



Open the foil pouch and ensure that the pellet is at the bottom of the vial before opening.

2

Rehydrate the lyophilized pellet with the appropriate buffer. A minimum volume of 100 μ l is recommended.



3



Vortex briefly to mix. Centrifuge to collect the rehydrated, inactivated target material at the bottom of the tube.

4

Use the appropriate volume for the assay being performed and follow laboratory protocols or manufacturer instructions for processing a sample. **Note:** Each pellet is intended as a single use test. Dilutions may be performed and used immediately. Storage of the rehydrated or diluted material is not recommended.