

# INSTRUCTIONS FOR USE



## ■ Helix Elite™ Molecular Standards for use with the BD MAX™ System

### INTENDED USE

Inactivated **Helix Elite™ Molecular Standards** are external controls suitable for use with the BD MAX™ assay.

### 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.

### PRINCIPLES

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

### COMPOSITION

The preparation consists of inactivated pathogen(s) stabilized in a proprietary matrix of excipients.

### WARNINGS AND PRECAUTIONS

- Do not open foil pouch until ready to 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](http://www.microbiologics.com) 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

- BD MAX™ assay and materials required per assay's instructions
- Package insert of the BD MAX™ assay
- Vortex mixer

## INSTRUCTIONS FOR USE

1. Read the package insert specific to the BD MAX™ assay.
2. Tear open pouch at notch. Remove the tube from the pouch and ensure that the pellet is at the bottom of the vial before opening the tube.
3. Uncap the tube and carefully transfer the pellet to the Sample Buffer Tube.
4. Vortex briefly for 5 seconds on high to mix.
5. Invert Sample Buffer Tube 5 times.
6. Vortex again for 5 seconds on high to mix.
7. Follow instructions listed in the BD package insert.

## 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



Caution, Consult Accompanying Documents



Counting



Health Hazard



In Vitro Medical Device



Manufacturer



Temperature Limitation



Use By



Refer to Instructions for Use



Telephone Number

## 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](http://www.microbiologics.com), for current technical information and product availability.

## ACKNOWLEDGEMENTS



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## ILLUSTRATED INSTRUCTIONS

1

Read the BD MAX™ package insert specific to the BD MAX™ assay.

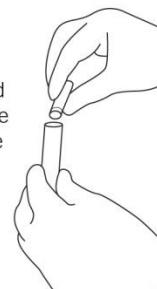
2

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



3

Uncap the tube and carefully transfer the pellet to the Sample Buffer Tube.

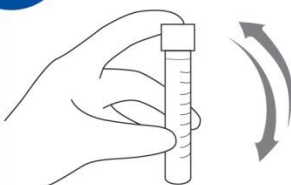


4

Vortex for 5 seconds on high to mix.



5



Invert Sample Buffer Tube 5 times.

6

Vortex for 5 seconds on high to mix.



7

Follow instructions listed in the BD package insert.