

INSTRUCTIONS FOR USE



Helix Elite™ Molecular Standards

INTENDED USE

Inactivated **Helix Elite™ Molecular Standards** are positive and negative controls suitable for use with Cepheid Xpert® Assay kits.

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 stable at 2°C - 25°C through the expiration date. Each swab 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 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

- Cepheid Xpert Assay kit and materials required per kit's instructions
- Package Insert of the Xpert Assay kit
- Vortex mixer

INSTRUCTIONS FOR USE

Preparation

1. Read the Cepheid package insert specific to the Xpert assay.
2. Tear open pouch at notch.
3. Remove the swab from the pouch.

A. Instructions for Sample Reagent Vial

4. Insert the swab into Sample Reagent vial provided in the Cepheid assay and break the swab by snapping the shaft.
5. Vortex the vial for 10 seconds at full speed to mix.
6. Use Cepheid transfer pipette or other sterile pipette to transfer the appropriate volume listed in the Cepheid package insert to transfer the prepared sample to the cartridge.
7. Close the cartridge lid and start the test.

B. Instructions for Transport Medium Vial

4. Insert the swab into the Transport Medium Vial of the required Collection Device and break the swab by snapping the shaft. If transport medium solution is not available, use 3 ml of nuclease-free water.
5. Vortex the vial for 10 seconds at full speed to mix.
6. Use Cepheid transfer pipette or other sterile pipette to transfer the appropriate volume listed in the Cepheid package insert to transfer the prepared sample to the cartridge.
7. Close the cartridge lid and start the test.

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 swab 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)



In Vitro Diagnostic Medical Device



Catalog Number



Manufacturer



Caution, Consult Accompanying Documents



Temperature Limitation



Consult Instructions for Use



Use By



Contains Sufficient for < n > Tests

PRODUCT WARRANTY

- These products are warranted to meet the specifications and performance printed and illustrated in the 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



Microbiologics, Inc.
200 Cooper Avenue North
St. Cloud, MN 56303 USA
www.microbiologics.com

Customer Service
Tel. 320-253-1640
U.S. Toll Free 800-599-BUGS (2847)
Email: info@microbiologics.com

Technical Support
Tel. 320-229-7045
U.S. Toll Free 866-286-6691
Email: techsupport@microbiologics.com

ILLUSTRATED INSTRUCTIONS

Preparation

1
Read the Cepheid package insert specific to the Xpert® assay.


2


Tear open pouch at notch.

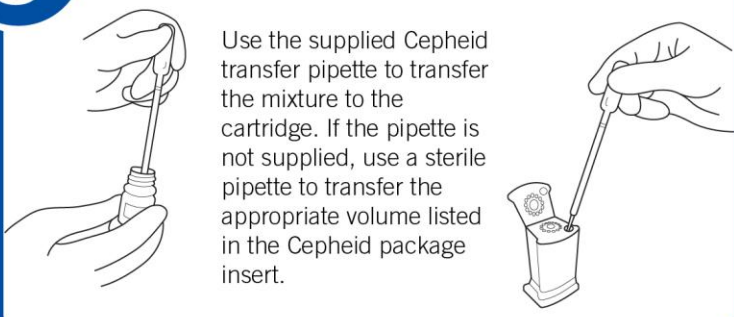
3


Remove the swab from the pouch.

A. Instructions for Sample Reagent Vial

4

Insert the swab into the Sample Reagent vial and break the swab by snapping the shaft.

5

Vortex the vial for 10 seconds.

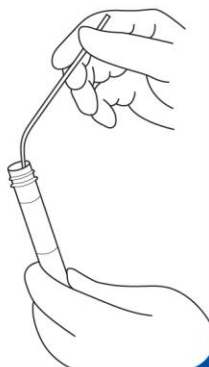
6

Use the supplied Cepheid transfer pipette to transfer the mixture to the cartridge. If the pipette is not supplied, use a sterile pipette to transfer the appropriate volume listed in the Cepheid package insert.

7

Close the cartridge and start the test.

B. Instructions for Transport Medium Vial

4

Insert the swab into the transport medium vial or 3 ml of nuclease-free water and break by snapping the shaft.



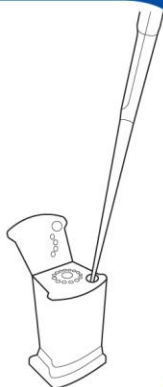
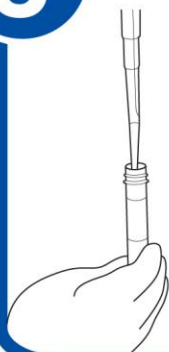
5

Vortex the vial for 10 seconds.



6

Use the supplied Cepheid transfer pipette to transfer the mixture to the cartridge. If the pipette is not supplied, use a sterile pipette to transfer the appropriate volume listed in the Cepheid package insert.



7

Close the cartridge and start the test.

