

INSTRUCTIONS FOR USE



Helix Elite™ Molecular Standards (Inactivated Pellet) Products

- Chlamydia
- Cytomegalovirus

INTENDED USE

Helix Elite™ Molecular Standards (Inactivated Pellet) and QC Sets and Panels - Helix Elite™ Molecular Standards (Inactivated Pellet) are intended for use as external controls for qualitative detection by molecular assays.

SUMMARY AND EXPLANATION

Molecular tests offer rapid and accurate results regarding the presence of an organism. Proper interpretation of a molecular test requires the use of a control. Helix Elite™ Molecular Standards (Inactivated Pellet) Products are easy-to-use process controls that can be used to monitor the extraction, amplification, and detection of 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

Helix Elite™ Molecular Standards (Inactivated Pellet) Products are comprised of cultured organisms inactivated by chemical, radiological, or heat treatments. Each pellet is packaged in a single-use foil pouch. Users should follow assay manufacturer or laboratory procedures for processing controls.

COMPOSITION

Helix Elite™ Molecular Standards (Inactivated Pellet) Products consist of individually packaged control material that contain inactivated pathogen(s) stabilized in a proprietary matrix of excipients.

The negative control for catalog number 8217 is a blank 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.
- Do not open foil pouch until ready to use.
- This product must be treated as a viable specimen and handled in accordance with Biosafety Level 2 practices as described in the United States Department of Health and Human Services Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH), Biosafety in Microbiological and Biomedical Laboratories, or other equivalent guidelines.
- 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 1.320.229.7045 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.
- Customer is responsible for ensuring compatibility of the control with the assay or protocol in use.

MATERIALS REQUIRED BUT NOT PROVIDED ---

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

INSTRUCTIONS FOR USE ---

Preparation

1. Read assay package insert, instructions for use, or applicable lab protocol.
2. Tear open pouch at notch.
3. Remove vial from pouch and ensure the pellet is at the bottom of the vial before opening.

A. Helix Elite™ Molecular Standards (Inactivated Pellet)

4. Rehydrate the lyophilized pellet with the appropriate buffer. A minimum volume of 100 µl is recommended.
5. Vortex the vial for 10 seconds at full speed to mix. Centrifuge to collect the rehydrated, inactivated target material at the bottom of the tube.
6. 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 for future use is not recommended.

B. QC Sets and Panels - Helix Elite™ Molecular Standards (Inactivated Pellet)

4. Rehydrate the lyophilized pellet by adding it to a tube or vial containing an appropriate buffer, transport media, or nuclease-free water. For minimum hydration volume:
 - Refer to the catalog number's product page at www.microbiologics.com or to the *QC Sets and Panels: Minimum Hydration Volumes* document at www.microbiologics.com, or
 - Contact Technical Support at 1.320.229.7045, U.S. Toll Free 1.866.286.6691, or techsupport@microbiologics.com.
5. Vortex the rehydrated pellet for 10 seconds or until pellet is dissolved.
6. Use the appropriate volume of the rehydrated pellet for the assay being performed and follow laboratory protocols or manufacturer instructions for processing the 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 for future use is not recommended.

STORAGE AND EXPIRATION

Store the Helix Elite™ Molecular Standards (Inactivated Pellet) Products at 2°C - 25°C in the original packaging up to the indicated expiration date. After opening the foil pouch use the pellet immediately. In-use stability of the rehydrated pellet at room temperature (21 °C) is 6 hours.

Helix Elite™ Molecular Standards (Inactivated Pellet) Products should not be used if:

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

ANALYTICAL PERFORMANCE

The performance of the Helix Elite™ Molecular Standards (Inactivated Pellet) and QC Sets and Panels - Helix Elite™ Molecular Standards (Inactivated Pellet) were evaluated in a study that was performed using three different production lots, three sites using three different instruments, and six different users. The results of the study are summarized below.

Analyte	Agreement (%) by Test Site			
	Site 1 ¹	Site 2 ¹	Site 3	Overall
<i>Chlamydia trachomatis</i>	30/30 (100)	30/30 (100)	30/30 (100)	90/90 (100)
<i>Neisseria gonorrhoeae</i>	30/30 (100)	30/30 (100)	29/30 (97)	89/90 (99)
<i>Trichomonas vaginalis</i>	30/30 (100)	30/30 (100)	30/30 (100)	90/90 (100)

¹Three Unresolved results were obtained; in all cases a new control was retested and the expected results were obtained.

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



Contains sufficient for <n> tests



In Vitro Medical Device



Authorized Representative in the European Community



CE Mark



Manufacturer



Temperature Limitation



Use By



Refer to Instructions for Use



Telephone Number



Positive Control



Negative Control

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

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

Technical Support

Tel. 1.320.229.7045
U.S. Toll Free 1.866.286.6691
Email: techsupport@microbiologics.com

Customer Service

Tel. 1.320.253.1640
U.S. Toll Free 1.800.599.BUGS (2847)
Email: info@microbiologics.com



MediMark® Europe
11, rue Emile Zola B.P. 2332
38033 Grenoble Cedex 2, France
Tel. 33 (0)4 76 86 43 22
Fax. 33 (0)4 76 17 19 82
Email. info@medimark-europe.com

ILLUSTRATED INSTRUCTIONS

Preparation

1

Read assay package insert, instructions for use, or applicable lab protocol.

2



Tear open pouch at notch.

3

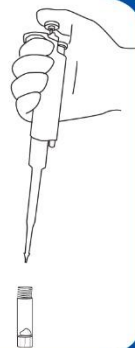
Remove vial from pouch and ensure the pellet is at the bottom of the vial before opening.



A. Helix Elite™ Molecular Standards (Inactivated Pellet)

4

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



5

Vortex the vial for 10 seconds at full speed to mix. Centrifuge to collect the rehydrated, inactivated target material at the bottom of the tube.



6

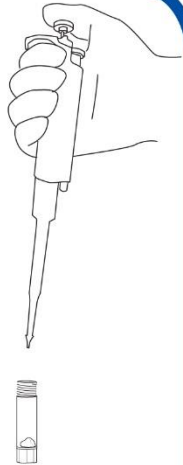
Use the appropriate volume for the assay being performed and follow laboratory protocols or manufacturer instructions for processing a sample.

Note: Each pellet is intended as a single use test. Dilutions may be performed and used immediately. Storage of the rehydrated or diluted material for future use is not recommended.

B. QC Sets and Panels - Helix Elite™ Molecular Standards (Inactivated Pellet)

4

Rehydrate the lyophilized pellet by adding it to a tube or vial containing an appropriate buffer, transport media, or nuclease-free water.



For minimum hydration volume:

- Refer to the catalog number's product page at www.microbiologics.com or to the *QC Sets and Panels: Minimum Hydration Volumes* document at www.microbiologics.com, or
- Contact Technical Support at 1.320.229.7045, U.S. Toll Free 1.866.286.6691, or techsupport@microbiologics.com.

5

Vortex the vial for 10 seconds at full speed to mix. Centrifuge to collect the rehydrated, inactivated target material at the bottom of the tube.



6

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 for future use is not recommended.