INSTRUCTIONS FOR USE

IVD CE 2797

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 control materials for qualitative detection of specific target analytes of interest in Table 1 by molecular assays. These controls are not intended to replace manufacturer's controls provided with the nucleic acid assay itself.

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.

Table 1: Helix Elite™ Molecular Standards (Inactivated Pellet) and QC Sets and Panels

Item Number	Item Name	Targets	Contents
HE0034N	Inactivated Chlamydia pneumoniae	Chlamydia pneumoniae	Contains five pellets
HE0035N	Inactivated Chlamydia trachomatis	Chlamydia trachomatis	Contains five pellets
HE0039N	Inactivated Cytomegalovirus Low Control	Cytomegalovirus	Contains five pellets
HE0040N	Inactivated Cytomegalovirus High Control	Cytomegalovirus	Contains five pellets
HE0045N	Inactivated Chlamydia trachomatis/Neisseria gonorrhoeae (CT/NG)	Chlamydia trachomatis, Neisseria gonorrhoeae	Contains five pellets

HELIX | ELITE™ MOLECULAR STANDARDS

Microbiologics® QC SETS AND PANELS

Item Number	Item Name	Targets	Contents
8217	Respiratory (21 Targets) Control Panel	**Positive Control**: Adenovirus Type 6, Bordetella parapertussis, Bordetella pertussis, Chlamydia pneumoniae, Coronavirus 229E, Coronavirus HKU1 surrogate, Coronavirus NL63 surrogate, Coronavirus OC43 surrogate Strain 1 and Coronavirus OC43 surrogate Strain 2, Human Metapneumovirus surrogate, Human Rhinovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H1-2009, Influenza A subtype H3, Influenza B, Mycoplasma pneumoniae, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4a surrogate, and Respiratory Syncytial Virus **Negative Control**: Blank Pellet	Contains six positive and six negative control pellets (12 vials/pellets total)
8228	CT/GC/TV Control Panel (Inactivated Pellet)	Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis	Contains six pellets

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.
- See QC Sets and Panels: Technical Information document at www.microbiologics.com for known extrinsic factors and interfering substances for each catalog number.
- 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.
- Not all instruments and assays are compatible with multi-target controls. 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. 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.
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: Technical Information 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
Chlamydia trachomatis	30/30 (100)	30/30 (100)	30/30 (100)	90/90 (100)
Neisseria gonorrhoeae	30/30 (100)	30/30 (100)	29/30 (97)	89/90 (99)
Trichomonas vaginalis	30/30 (100)	30/30 (100)	30/30 (100)	90/90 (100)

[1]Three 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

LOT	Batch Code (Lot)		Manufacturer
REF	Catalog Number		Temperature Limitation
	Caution, Consult Accompanying Documents		Use By
Σ	Contains sufficient for <n> tests		Refer to Instructions for Use
IVD	In Vitro Medical Device		Telephone Number
EC REP	Authorized Representative in the European Community	CONTROL +	Positive Control
CE	CE Mark	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

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ILLUSTRATED INSTRUCTIONS

Preparation

1

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

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.

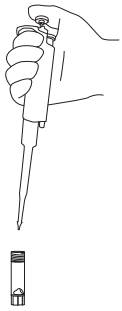
3

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

A. Helix Elite™ Molecular Standards (Inactivated Pellet)

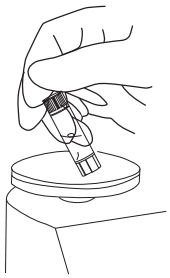
4

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.

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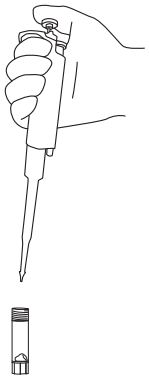
Microbiologics

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:

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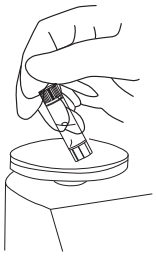
- Contact Technical Support at 1.320.229.7045, U.S. Toll Free 1.866.286.6691, or techsupport@microbiologics.com.

5

Vortex the vial for 10 seconds at full speed to mix.



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