INSTRUCTIONS FOR USE

IVD CE 2797

Helix Elite™ Molecular Standards (Inactivated Swabs) Products

- **Chlamydia**
- **Cytomegalovirus**

HELIX|ELITE™ MOLECULAR STANDARDS

Microbiologics® QC SETS AND PANELS

INTENDED USE

Helix Elite™ Molecular Standards (Inactivated Swabs) Products 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 and quantity of an organism. Proper interpretation of a molecular test requires the use of a control. Helix Elite™ Molecular Standards (Inactivated Swabs) 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

Helix Elite™ Molecular Standards (Inactivated Swabs) are intact pathogens inactivated by chemical, radiological, or temperature treatments. Each swab 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 Swabs) consist of individually packaged control swabs that contain inactivated pathogen(s) stabilized in a proprietary matrix of excipients.

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 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

INSTRUCTIONS FOR USE

Preparation

1. Read assay package insert, instructions for use, or applicable lab protocol.
2. Tear open pouch at notch.
3. Remove the swab from the pouch.

Minimum Hydration Volume

For the 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.

Note: Each swab 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.

A. Instructions for Sample Preparation Reagent

4. Insert the swab into the Sample Preparation Reagent provided in the assay and break the swab by snapping the shaft.
5. Vortex or vigorously shake for 10 seconds.
6. Use transfer pipette provided in the assay or other sterile pipette to transfer the appropriate volume listed in the assay package insert to transfer the prepared sample to assay cartridge.
7. Process test according to manufacturer's instructions.

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 nuclease-free water.
5. Vortex or vigorously shake the vial for 10 seconds.
6. Use transfer pipette provided in the assay or other sterile pipette to transfer the appropriate volume listed in the assay package insert to transfer the prepared sample to the cartridge.
7. Process test according to manufacturer's instructions.

C. Instructions for Direct Inoculation with Dry or Pre-Wet Swab

4. Insert the dry or pre-wet swab into the cartridge and break the swab by snapping the shaft.
5. Proceed with assay according to manufacturer's instructions and timeline.

STORAGE AND EXPIRATION

Store the Helix Elite™ Molecular Standards (Inactivated Swabs) at 2°C - 25°C in the original packaging up to the indicated expiration date. After opening the foil pouch, use the swab immediately. In-use stability of the rehydrated swab at room temperature (21°C) is 5 hours.

Helix Elite™ Molecular Standards (Inactivated Swabs) 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 *Chlamydia trachomatis/Neisseria gonorrhoeae* (CT/NG) Control Panel (Inactivated Swab) was 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.

Positive Target	Agreement (%) with Expected Results, by Test Site			
	Site 1 [1, 4]	Site 2 [2, 4]	Site 3	Overall
C. trachomatis	31/31 (100)	31/31 (100)	30/30 (100)	92/92 (100)
N. gonorrhoeae (NG2)	31/31 (100)	31/31 (100)	30/30 (100)	92/92 (100)
N. gonorrhoeae (NG4)	31/31 (100)	31/31 (100)	30/30 (100)	92/92 (100)
SPC[3]	31/31 (100)	31/31 (100)	30/30 (100)	92/92 (100)

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

2 Two ERROR results and one INVALID result were obtained; in all cases a new control was retested and the expected results were obtained.

3 SPC: Sample Processing Control

4 More than 30 measurements were taken as extra positive controls were ran during re-tests of negative controls.

Negative Target	Agreement (%) with Expected Results, by Test Site			
	Site 1 [1,2, 3]	Site 2[2, 3]	Site 3	Overall
SAC	33/33 (100)	34/34 (100)	30/30 (100)	97/97 (100)
SPC	33/33 (100)	34/34 (100)	30/30 (100)	97/97 (100)

1 Two ERROR results were observed at Site 1; in all cases a new control was retested and the expected results were obtained.

2 One Negative Control at Site 1 and two Negative Controls at Site 2 generated a positive result for NG2 target, however the qualitative results were negative in each case because the assay requires both NG2 and NG4 targets to be positive in order to return a positive result for NG. In accordance with the assay protocol, the work area was cleaned and the controls were retested.

3 More than 30 measurements were taken as extra negative controls were ran during re-tests of positive controls.

Site	Mean Ct (%CV) Positive Control		
	CT1	NG2	NG4
1	31.3 (1.3)	31.2 (1.4)	30.6 (1.5)
2	31.2 (2.6)	31.8 (2.1)	31.1 (2.6)
3	33.0 (3.9)	33.4 (4.1)	32.5 (4.0)
All Sites	31.8 (3.8)	32.1 (4.0)	31.4 (3.9)

%CV: Percent Coefficient of Variation; SPC: Sample Processing Control

Site	Mean Ct (%CV) Negative Control	
	SAC	SPC
1	27.3 (1.8)	31.6 (0.9)
2	27.7 (1.8)	31.4 (0.7)
3	28.8 (4.1)	31.5 (0.5)
All Sites	27.9 (3.5)	31.5 (0.7)

%CV: Percent Coefficient of Variation; SAC: Sample Adequacy Control; SPC: Sample Processing Control

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)
REF	Catalog Number
	Caution, Consult Accompanying Documents
	Consult Instructions for Use
Σ	Contains Sufficient for < n > Tests
CONTROL +	Positive Control
CONTROL -	Negative Control
CE	CE Mark
IVD	*In Vitro* Diagnostic Medical Device
	Manufacturer
	Temperature Limitation
	Use By
EC REP	Authorized Representative in the European Community

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.

WEBSITE

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

ACKNOWLEDGEMENTS

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ILLUSTRATED INSTRUCTIONS

Preparation

Minimum Hydration Volume

For the minimum hydration volume:

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A. Instructions for Sample Preparation Reagent

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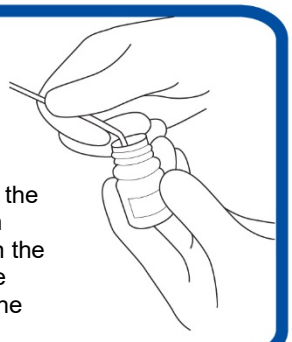
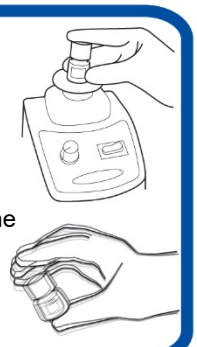
Insert the swab into the Sample Preparation Reagent provided in the assay and break the swab by snapping the shaft.



5

Vortex or vigorously shake the vial for 10 seconds.



6

Use transfer pipette provided in the assay or other sterile pipette to transfer the appropriate volume listed in the assay package insert to transfer the prepared sample to assay cartridge.

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Process test according to manufacturer's instructions.

B. Instructions for Transport Medium Vial

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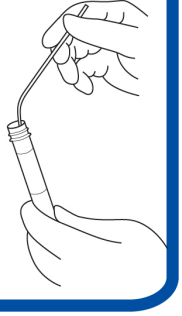
Insert the swab into the Transport Medium Vial of the required Collection Device and break the swab by snapping the shaft. If transport medium solution is not available, use nuclease-free water.



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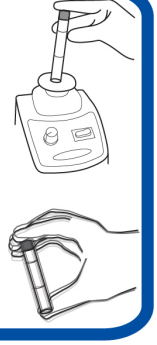

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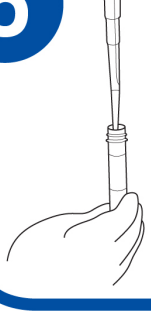

Use transfer pipette provided in the assay or other sterile pipette to transfer the appropriate volume listed in the assay package insert to transfer the prepared sample to the cartridge.

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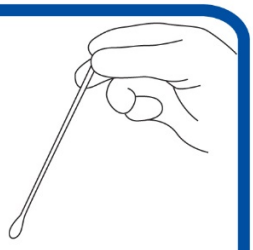
Process test according to manufacturer's instructions.

C. Instructions for Direct Inoculation with Dry or Pre-Wet Swab

4



Insert the dry or pre-wet swab into the cartridge and break the swab by snapping the shaft.

5

Proceed with assay according to manufacturer's instructions and timeline.

Microbiologics®
A safer, healthier world.