

INSTRUCTIONS FOR USE



■ Inactivated Helix Elite™ Molecular Standards (Inactivated Swab)

INTENDED USE

The Inactivated Helix Elite™ Molecular Standards are intended for use as non-viable, external, positive control materials to evaluate the performance of nucleic acid amplification testing (NAAT) procedures that detect the analytes in Annex 1. These products have no qualitative or quantitative assigned value. These control materials are nonautomated and not intended to be used for screening, monitoring, or diagnosis. These controls are not intended for any specific patient population or specimen.

SUMMARY AND PRINCIPLES

The Inactivated Helix Elite™ Molecular Standards can be used to monitor the extraction, amplification and detection process of molecular testing assays that include the analytes in Annex 1. Routine use of quality controls monitor test variation, lot-to-lot test kit performance, operator performance, and aid in identifying random or systemic error.

COMPOSITION

The Inactivated Helix Elite™ Molecular Standards consist of 6 individually packaged lyophilized swabs. The analytes in Annex 1 have been inactivated using thermal treatments.

The Inactivated Helix Elite™ Molecular Standards are lyophilized in a PCR compatible matrix. The organisms are prepared in a buffered solution with materials of plant and animal origin, preservatives, and stabilizers. The solution is lyophilized into a ready-to-use swab.

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.
- The inactivated lyophilized swabs are single-use only. Once hydrated, do not freeze for reuse. If reused, the inactivated lyophilized swabs may not perform as expected including, but not limited to, degradation or over-dilution of material resulting in false negative results, contamination resulting in false positive results or positive detection of organisms not on the swab, and environmental contamination.
- Do not open foil pouch until ready to use.
- Although this product has been inactivated, there is no known test or inactivation method that can assure that it will not transmit infection. This product must be treated as a potential biohazard. Wear appropriate personal protective equipment. Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are handled. Disinfect any spills, and dispose of all materials in accordance with national and local regulations.
- 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 Customer Service at info@microbiologics.com.
- These products do not contain any hazardous substances listed in 1272/2008/EC.
- Report any serious incident that has occurred in relation to the device to Microbiologics and the local regulatory officials in which the user and/or the patient is established.

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, rehydrate and use immediately. In-use stability of the rehydrated swab at room temperature (25°C) is 5 hours.



The 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
- Packaging is damaged

MATERIALS REQUIRED BUT NOT PROVIDED

- Nucleic acid extraction kit and assay
- Instrumentation for detection
- Rehydration fluid/buffer such as sample reagent tube as required by assay to be performed
- Pipettors capable of delivering 0.5-1000 µl volumes
- Nuclease-free aerosol barrier pipette tips
- Vortex

INSTRUCTIONS FOR USE

Preparation

1. Read package insert, instructions for use or lab protocol for the applicable assay. 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 swab from pouch and process further using instructions A or B below. Consult assay product insert for guidance on processing QC samples and patient samples.

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

4. Insert the swab as instructed by the assay manufacturer. See illustrated instructions on page 5.
 - a. If protocol instructs to break the swab, insert the swab into the device, lift the swab up slightly from the bottom of the device and break/snap the swab to the right by pushing the shaft of the swab against the opening of the device. The break point should be appropriate to the size of the test device or vial.
5. Process following assay instructions for use.

B. Instructions for Placing Swab into a Vial/Tube of Hydrating Fluid/Buffer

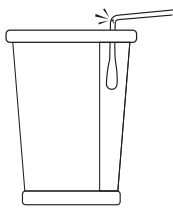
4. Place swab into the vial/tube of hydration fluid/buffer recommended by the assay manufacturer.
 - a. If not using a provided hydration fluid/buffer from the assay manufacturer, please refer to Table 1 below for sample volume and known extrinsic factors and interfering substances.
5. Break the swab by lifting the swab a few millimeters from the bottom of the vial/tube and pushing the shaft of the swab against the rim to break it.
6. Recap the vial/tube and vortex for 10 seconds or until swab is hydrated.
7. Use the appropriate volume for the assay being performed and follow laboratory protocols or manufacturer instructions for processing a sample.
8. Note: Dilutions may be performed and used immediately. Storage of diluted material for future use is not recommended

Table 1: Sample Volume

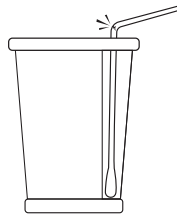
Hydration Fluid/Buffer	Minimum Hydration Volume	Mix Format/Time	Known Extrinsic Factors and interfering Substances
Sample Reagent Tube	2000 µl	Vortex for 10 seconds	N/A

LIMITATIONS

- When breaking the control swab, if left too short for the test device or vial/tube, the swab may be jostled and not make sufficient contact with reagents. If swab is left too long, the swab shaft may compromise the integrity of the test device or vial/tube by preventing proper closure. Do NOT cut shaft as contamination may occur.



Swab left too short
Do NOT use.



Swab left too long. Do NOT use. Do NOT cut shaft to length. Start process over with new swab.

- These products are unassayed control material. They may not be suitable for use with all kits and procedures as not all instruments and assays are compatible with multi-target controls. Customer is responsible for verifying the performance of this product with their chosen instrumentation and assay(s). As a third-party control manufacturer, Microbiologics' provides quality controls that deliver an independent, unbiased assessment of performance with any instrument or method. While not intended to replace control materials provided by the assay/instrument supplier, third-party control materials should be considered.
- Target concentrations of each analyte are specific to Microbiologics' assay method and procedures. These organisms are intact, non-viable, and may be used with any PCR-based test or assay. Microbiologics guarantees each nucleic acid is present and can be amplified but does not guarantee specific analyte concentrations. Each laboratory should establish its own range of acceptable values on their assay system per their internal quality assurance procedure/program. Nucleic acid reactivity, which may vary over time, is dependent on a laboratory's instrumentation, assay method, procedures, calibration, or technician. Microbiologics' molecular controls are not calibrators and should not be used for assay calibration or as an absolute reference material.

MICROBIOLOGICAL STATE

These products were prepared using suitable inactivation methods. While they have been tested for innocuity, universal laboratory precautions are recommended, and material should be treated as though it was a viable specimen.

KEY OF SYMBOLS

	Authorized Representative in the European Community / European Union		In vitro diagnostic medical device
	Batch code (Lot)		Manufacturer
	Biological risks		Negative control
	Catalog number		Positive control
	Caution		Quantity
	CE mark		Swiss Authorized Representative
	Consult instructions for use or consult electronic instructions for use		Telephone number
	Contains sufficient for <n> tests		Temperature limit
	Device for near-patient testing		UK Conformity Assessed mark
	Do not re-use		UK Responsible Person
	Do not use if package is damaged and consult instructions for use		Use-by-date
	Health hazard		Water; Fluid
	EU Authorized Representative		

Please refer to product labels for applicable symbols.

NOTICE TO PURCHASERS

The purchase of these products 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 these products.

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WEBSITE

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

ASSISTANCE



Microbiologics, Inc.

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

Customer Service

Tel: +1.320.253.7400
U.S. Toll Free: +1.800.599.2847
Email: info@microbiologics.com

Technical Support

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



MediMark® Europe

11 rue Emile Zola
38100 Grenoble, France
Tel: +33 (0)4 76 86 43 22
Fax: +33 (0)4 76 17 19 82
Email: info@medimark-europe.com



International Associates Limited

Centrum House, 38 Queen Street,
Glasgow, Lanarkshire, G1 3DX, UK
UKRP@ia-uk.com



Decomplex AG

Freiburgstrasse 3, 3010
Bern, Switzerland

Additional copies of this product insert may be obtained at www.microbiologics.com or by emailing info@microbiologics.com

ILLUSTRATED INSTRUCTIONS

1

Preparation



Read package insert, instructions for use or lab protocol for the applicable assay. 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 swab from pouch and process further using instructions A or B. Consult assay product insert for guidance on processing QC samples and patient samples.

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

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Insert the swab as instructed by the assay manufacturer.

If protocol instructs to break the swab, insert the swab into the device, lift the swab up slightly from the bottom of the device and break/snap the swab to the right by pushing the shaft of the swab against the opening of the device. The break point should be appropriate to the size of the test device or vial.



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Process following assay instructions for use.

B. Instructions for Placing Swab into a Vial/Tube of Hydrating Fluid/Buffer

4

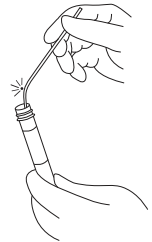
Place swab into the vial/tube of hydration fluid/buffer recommended by the assay manufacturer.

If not using a provided hydration fluid/buffer from the assay manufacturer, please refer to Table 1 below for sample volume and known extrinsic factors and interfering substances.



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Break the swab by lifting the swab a few millimeters from the bottom of the vial/tube and pushing the shaft of the swab against the rim to break it.

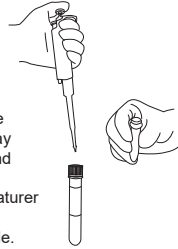


6



Recap the vial/tube and vortex for 10 seconds or until swab is hydrated.

7



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

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Note: Dilutions may be performed and used immediately. Storage of diluted material for future use is not recommended.



REVISION HISTORY ---

Publication History		
Revision	Date	Description of Change
A	2023-06-13	Initial release to IVDR
B	2025-10	Updated MediMark® Address and replaced EC Rep Symbol with EU Rep.

ANNEX 1 SUMMARY OF ANALYTES ---

Item #	Item Name	Analytes	Input Concentration (copies/swab)*	Inactivation Method
HE0053NS	Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA) Inactivated Swab	Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA)	10 ³	Thermal
HE0054NS	Methicillin-Susceptible <i>Staphylococcus aureus</i> (MSSA) Inactivated Swab	Methicillin-Susceptible <i>Staphylococcus aureus</i> (MSSA)	10 ²	Thermal
HE0055NS	Methicillin-Susceptible <i>Staphylococcus epidermidis</i> (MSSE) Inactivated Swab	Methicillin-Susceptible <i>Staphylococcus epidermidis</i> (MSSE)	10 ⁴	Thermal

*These are input concentrations and are not representative of recoverable concentrations or expected values.

