

# INSTRUCTIONS FOR USE



## ■ 8255 Multiplex Vaginal Control Panel

### INTENDED USE

The Multiplex Vaginal Control Panel is intended for use as non-viable, external, positive, and negative control material to evaluate the performance of nucleic acid amplification testing (NAAT) procedures that detect the analytes in Table 1. This product has no qualitative or quantitative assigned value. This control material is nonautomated and not intended to be used for screening, monitoring, or diagnosis. This control is not intended for any specific patient population or specimen.

### SUMMARY AND PRINCIPLES

The Multiplex Vaginal Control Panel can be used to monitor the extraction, amplification, and detection process of molecular testing assays that include the analytes in Table 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 Multiplex Vaginal Control Panel consists of 12 individually packaged lyophilized swabs: six positive control swabs and six negative control swabs. The analytes in Table 1 have been inactivated using thermal treatments.

The Multiplex Vaginal Control Panel is 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.

Table 1: Contents of the Multiplex Vaginal Control Panel

Analytes*
<b>Positive Control</b>
<i>Atopobium vaginae</i>
Bacterial Vaginosis-Associated Bacterium 2 (BVAB2) surrogate
<i>Candida albicans</i>
<i>Candida glabrata</i>
<i>Trichomonas vaginalis</i>
<b>Negative Control</b>
<i>Lactobacillus acidophilus</i>

\*All analytes are added at a concentration of  $10^3$  -  $10^7$  copies per swab

### WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic use only.
- To be used by personnel trained in use of the assay and in the disposal of biohazardous materials.
- The inactivated lyophilized swabs are single-use only. If 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, or environmental contamination resulting in detection of organisms not on the swab.
- 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](http://www.microbiologics.com) or by contacting Technical Support at 1.320.229.7045 or U.S. Toll Free 1.866.286.6691.
- This product does 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 Multiplex Vaginal Control Panel 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 6 hours.

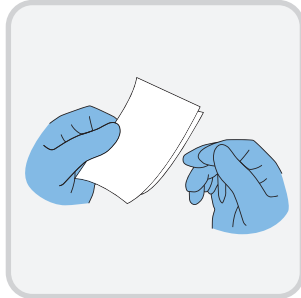
The Multiplex Vaginal Control Panel should not be used if:

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

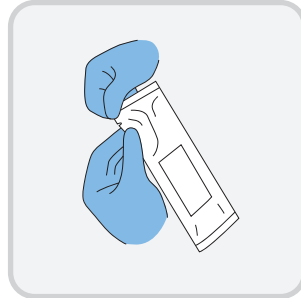
## MATERIALS REQUIRED BUT NOT PROVIDED

- Assay for detection including required instrumentation and consumables.
- Rehydration buffer such as transport reagent tube as required by assay to be performed
- Pipettors capable of delivering 0.5-1000 µl volumes (if applicable)
- Nuclease-free aerosol barrier pipette tips (if applicable)

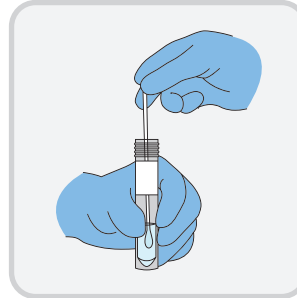
## INSTRUCTIONS FOR USE



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.



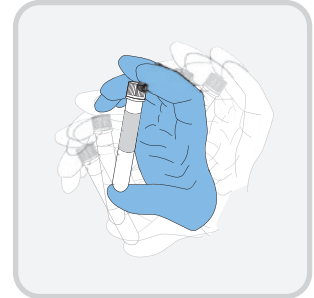
2. Tear open pouch at notch and remove swab from pouch.



3. Place swab into the provided hydration fluid/buffer from the assay manufacturer.

If hydration fluid/buffer is not provided by the assay manufacturer, transport medium may be used. A minimum volume of 300 µl is needed to hydrate the swab.

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. If the swab is left too short for the test device or vial, 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 by preventing proper closure. Do NOT cut shaft as contamination may occur, start process over with new swab.



4. Recap the vial/tube and shake vigorously 3-4 times or until the swab is hydrated.

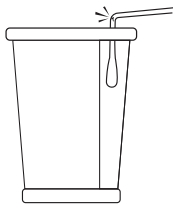
5. Use the appropriate volume for the assay being performed and follow laboratory protocols or manufacturer instructions for processing a sample.

## TECHNICAL NOTE

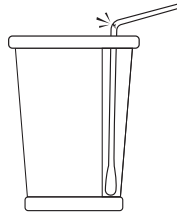
Use of external verification panels are highly recommended such as Microbiologics 8245 Multiplex Vaginal Verification Panel.

## LIMITATIONS

- There are no known extrinsic factors or interfering substances specific to this product. Please consult assay instructions for use for any extrinsic factors or interfering substances.
- 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 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.

- This product is unassayed control material. It 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

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

 <b>EC REP</b>	Authorized Representative in the European Community		Health Hazard
 <b>LOT</b>	Batch Code (Lot)	 <b>IVD</b>	In Vitro Diagnostic Medical Device
	Biological Risks		Manufacturer
 <b>REF</b>	Catalog Number	 <b>CONTROL -</b>	Negative Control
	Caution	 <b>CONTROL +</b>	Positive Control
	CE Mark	 <b>QTY</b>	Quantity
	Consult instructions for use or consult electronic instructions for use		Telephone Number
	Contains sufficient for <n> tests		Temperature Limit
	Do not re-use		Use-By Date
	Do not use if package is damaged and consult instructions for use		Device for near-patient testing

Please refer to product labels for applicable symbols.

## 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](http://www.microbiologics.com), for current technical information and product availability.

## ASSISTANCE

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Additional copies of this product insert may be obtained at [www.microbiologics.com](http://www.microbiologics.com) or by emailing [info@microbiologics.com](mailto:info@microbiologics.com)

## REVISION HISTORY ---

Publication History		
Revision	Date	Description of Change
A	2022-03-24	Initial release
B	2023-12-04	Removed "For professional use only" statement. Added "To be used by personnel trained in use of the assay and in the disposal of biohazardous materials. Expanded on "...do not freeze for reuse" statement in Warnings and Precautions section. Adjusted order of sections: Storage and Expiration and Limitations. Removed sections: Performance Characteristics (added verbiage to Limitations section) and Product Warranty. Removed Illustrated Instructions for Use section/move images to Instructions for Use section. Added extrinsic factors and interfering substances statement to Limitations section.

