

# INSTRUCTIONS FOR USE



## ■ 8245 Multiplex Vaginal Verification Panel

### INTENDED USE

The Multiplex Vaginal Verification 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 Verification 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 Verification Panel consists of 10 individually packaged lyophilized swabs: two swabs of positive control 1, two swabs of positive control 2, two swabs of positive control 3, two swabs of positive control 4, and two swabs of the negative control. The analytes in Table 1 have been inactivated using thermal treatments.

The Multiplex Vaginal Verification 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 Verification Panel

Analytes*
<b>Positive Control 1</b>
<i>Atopobium vaginae</i>
Bacterial Vaginosis-Associated Bacterium 2 (BVAB2) surrogate
<b>Positive Control 2</b>
<i>Candida albicans</i>
<b>Positive Control 3</b>
<i>Candida glabrata</i>
<b>Positive Control 4</b>
<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.
- 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.



- 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.
- This product is not made with natural rubber latex.
- 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.

## MATERIALS REQUIRED BUT NOT PROVIDED ---

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

## 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.
4. Place swab into a transport reagent tube.
  - a. Sample Volume (required assay volume + minimum hydration volume of 300 µl).
    - i. For known extrinsic factors and interfering substances, please refer to Table 2 below.
5. Break the swab by lifting the swab a few millimeters from the bottom of the tube and pushing the shaft of the swab against the rim to break it.
6. Recap the tube and shake vigorously 3-4 times 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 2: Sample Volume

Hydration Buffer	Minimum Hydration Volume	Mix Format/Time	Known Extrinsic Factors and interfering Substances
Transport Reagent Tube	300 µl	Shake vigorously 3-4 times	N/A

## TECHNICAL NOTE ---

- Use of external quality controls are highly recommended such as Microbiologics 8255 Multiplex Vaginal Control Panel.

## STORAGE AND EXPIRATION



Store the Multiplex Vaginal Verification 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 Verification 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

## PERFORMANCE CHARACTERISTICS

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.

## LIMITATIONS

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.

## 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



Authorized Representative in the European Community



Batch Code (Lot)



Biological Risks



Catalog Number



Caution



CE Mark



Consult instructions for use or consult electronic instructions for use



Contains sufficient for <n> tests



Do not re-use



Do not use if package is damaged and consult instructions for use



Health Hazard



In Vitro Diagnostic Medical Device



Manufacturer



Negative Control



Positive Control



Quantity



Telephone Number



Temperature Limit



Use-By Date

*Please refer to product labels for applicable symbols.*

## PRODUCT WARRANTY

These products are covered under warranty 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.
- The rehydrated material is frozen, Microbiologics cannot guarantee the stated characteristics of the product.

## 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)

## ILLUSTRATED INSTRUCTIONS

Each kit consists of 10 individually packaged lyophilized swabs: 4 positive control pools with 2 swabs of each and 2 swabs of the negative control.


1

**Preparation**



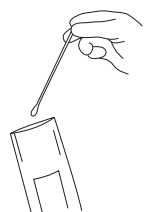
Read package insert, instructions for use or lab protocol for the applicable assay. Some instruments and assays are equipped with special QC settings. In these instances, it may be necessary to use the special setting when using QC sets and panels.

2



Tear open pouch at notch.

3



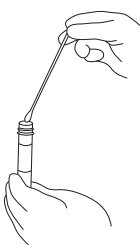
Remove swab from pouch.

4

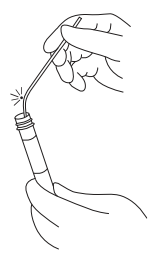
Place swab into a transport reagent tube.

Sample Volume (required assay volume + minimum hydration volume of 300 µl).

For known extrinsic factors and interfering substances, please refer to Table 2.




5



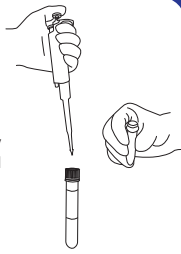
Break the swab by lifting the swab a few millimeters from the bottom of the tube and pushing the shaft of the swab against the rim to break it.

6



Recap the tube and shake vigorously 3-4 times 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.

## REVISION HISTORY ---

Publication History		
Revision	Date	Description of Change
A	28.MAY.2021	Initial release
B	18.JUN.2021	Removed italics from Bacterial Vaginosis-Associated Bacterium 2 (BVAB2) in table 1. Added "surrogate" to Bacterial Vaginosis-Associated Bacterium 2 (BVAB2) in table 1.
C	11.MAR.2022	Updated product configuration to add clarity, updated inactivation method to add clarity, added statement: "this product does not contain any hazardous substances listed in 1272/2008/EC," added technical note section, updated instructions for use, updated customer service telephone number.