

INSTRUCTIONS FOR USE



8249 Bacterial Vaginosis Control Panel

INTENDED USE

The Bacterial Vaginosis 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 Bacterial Vaginosis 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 monitors test variation, lot-to-lot test kit performance, operator performance, and aid in identifying random or systemic error.

COMPOSITION

The Bacterial Vaginosis Control Panel consists of 6 individually packaged lyophilized positive control pellets and 6 individually packaged lyophilized negative control pellets. The analytes in Table 1 have been inactivated using irradiation, chemical, and/or thermal treatments.

The Bacterial Vaginosis 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 pellet.

Table 1: Contents of the Bacterial Vaginosis Control Panel

| Analytes* |
|--------------------------------|
| Positive Control |
| <i>Atopobium vaginae</i> |
| <i>Gardnerella vaginalis</i> |
| Negative Control |
| <i>Lactobacillus crispatus</i> |

*Analytes are added at a concentration of 10^9 – 10^{10} RNA copies per pellet (positive control) and 10^4 – 10^5 DNA copies per pellet (negative control).

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 pellets 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 or by contacting Technical Support at 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 Bacterial Vaginosis Control Panel at 2°C - 25°C in the original packaging up to the indicated expiration date. After opening the foil, rehydrate and use immediately. In-use stability of the rehydrated pellet at room temperature (25°C) is 6 hours.

The Bacterial Vaginosis 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

- Nucleic acid extraction kit and assay
- Instrumentation for detection
- Rehydration buffer such as nuclease-free water or specimen transport medium (STM) buffer as required by assay to be performed.
- Pipettors capable of delivering 0.5-1000 µl volumes
- Nuclease-free aerosol barrier pipette tips
- Vortex
- Microcentrifuge (optional)

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. Remove vial from pouch and ensure the pellet is at the bottom of the vial before opening.
3. Hydrate the lyophilized pellet into a vial of nuclease-free water or specimen transport medium (STM) buffer.
 - a. For sample volume and known extrinsic factors and interfering substances, please refer to Table 2 below.
4. Recap the vial and vortex for 10 seconds at full speed to mix.
5. If a centrifuge is not available, tap the capped vial on a rigid surface to collect material at the bottom of the vial.
 - a. Alternatively, centrifuge briefly to collect any droplets clinging to the cap or upper walls of the vial.
6. Use the appropriate volume for the assay being performed and follow laboratory protocols or manufacturer instructions for processing a sample.
7. 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 |
|--|--------------------------|-----------------------|--|
| Nuclease-Free Water | 100 µl | Vortex for 10 seconds | N/A |
| Specimen Transport Medium (STM) Buffer | 2900 µl | Vortex for 10 seconds | N/A |

























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.
- 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

| | | | |
|---|---|---|------------------------------------|
|  | Authorized Representative in the European Community |  | 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 |
|  | 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 |
|  | UKCA Marking |  | EU Authorized Representative |

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, for current technical information and product availability.

BIBLIOGRAPHY

- Verhelst, R., Verstraelen, H., et al. (2004). Cloning of 16S rRNA genes amplified from normal and disturbed vaginal microflora suggests a strong association between Atopobium vaginae, Gardnerella vaginalis and bacterial vaginosis. *BMC microbiology*, 4, 16. doi.org/10.1186/1471-2180-4-16
- Savicheva, A. M. (2024). Molecular Testing for the Diagnosis of Bacterial Vaginosis. *International Journal of Molecular Sciences*, 25(1), 449. doi.org/10.3390/ijms25010449

ASSISTANCE



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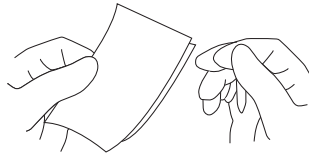
Additional copies of this product insert may be obtained at www.microbiologics.com or by emailing info@microbiologics.com.

ILLUSTRATED INSTRUCTIONS

Each kit consists of 6 individually packaged lyophilized positive control pellets and 6 individually packaged lyophilized negative control pellets.

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

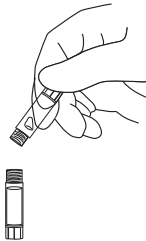
Tear open pouch at notch. Remove vial from pouch and ensure the pellet is at the bottom of the vial before opening.



3

Hydrate the lyophilized pellet into a vial of nuclease-free water or specimen transport medium (STM) buffer.

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



4

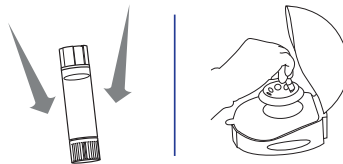
Recap the vial and vortex for 10 seconds at full speed to mix.



5

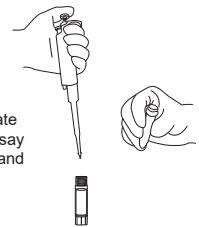
If a centrifuge is not available, tap the capped vial on a rigid surface to collect material at the bottom of the vial.

Alternatively, centrifuge briefly to collect any droplets clinging to the cap or upper walls of the vial.



6

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



7

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 | 2024-11-04 | Initial release |
| B | 2025-09 | Added Bibliography section, updated MediMark® Address and replaced EC rep Symbol with EU Rep. |