

# INSTRUCTIONS FOR USE



## ■ 8258 Rapid Group B Streptococcus (GBS) Verification Panel

## ■ 8242 Rapid Group B Streptococcus (GBS) Control Panel

### INTENDED USE

The Rapid Group B Streptococcus (GBS) Verification Panel and Rapid Group B Streptococcus (GBS) Control Panel are intended for use as non-viable, external, positive, and negative control materials to evaluate the performance of nucleic acid amplification testing (NAAT) procedures that detect Group B Streptococcus (GBS, *Streptococcus agalactiae*) in direct specimens. These products have no qualitative or quantitative assigned values. They are nonautomated and not intended to be used for screening, monitoring, or diagnosis. These products are not intended for any specific patient population or specimen.

### SUMMARY AND PRINCIPLES

The Rapid Group B Streptococcus (GBS) Verification Panel and Rapid Group B Streptococcus (GBS) 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 Rapid Group B Streptococcus (GBS) Verification Panel consists of 10 individually packaged lyophilized positive control swabs and 10 individually packaged lyophilized negative control swabs. The Rapid Group B Streptococcus (GBS) Control Panel consists of 6 individually packaged lyophilized positive control swabs and 6 individually packaged lyophilized negative control swabs. The analytes in Table 1 have been inactivated using thermal treatments.

The Rapid Group B Streptococcus (GBS) Verification Panel and Rapid Group B Streptococcus (GBS) Control Panel are lyophilized in a PCR compatible matrix. The organisms are prepared in a buffered solution with materials of plant origin, preservatives, and stabilizers. The solution is lyophilized into a ready-to-use swab.

**Table 1:** Contents of the Rapid Group B Streptococcus (GBS) Verification Panel and Rapid Group B Streptococcus (GBS) Control Panel

Rapid Group B Streptococcus (GBS) Verification Panel and Rapid Group B Streptococcus (GBS) Control Panel*
<b>Positive Control Swab</b>
Group B Streptococcus ( <i>Streptococcus agalactiae</i> )
<b>Negative Control Swab**</b>
<i>Lactobacillus acidophilus</i>
<i>Escherichia coli</i> surrogate for sample adequacy control***

\*All analytes are added at a concentration of  $10^2$  -  $10^6$  copies per swab. These are input concentrations and are not representative of recoverable concentrations or expected values.

\*\*Targets in the Negative Control Swab are not intended to be used as a positive control.

\*\*\*Sample adequacy control may not be applicable to all assays.



## WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic use only.
- To be used by personnel authorized to perform assay testing.
- 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, 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](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.
- An error may occur on the assay if the swab shaft remains too long upon snapping as this may affect the assay integrity. Do not use if the test device lid bulges or lid does not close.
- 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

- Assay for detection

## INSTRUCTIONS FOR USE

1. Read package insert, instructions for use or laboratory 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. 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. 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.
5. Process following assay instructions for use.

## STORAGE AND EXPIRATION



Store the Rapid Group B Streptococcus (GBS) Verification Panel and Rapid Group B Streptococcus (GBS) Control Panel at 2°C-25°C in the original packaging up to the indicated expiration date. After opening the foil pouch, use immediately. In-use stability of the swab after removing from the foil pouch at room temperature (15°C-25°C) is 1 hour.

The Rapid Group B Streptococcus (GBS) Verification Panel and Rapid Group B Streptococcus (GBS) 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

## 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 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 designated calibrators and should, therefore, not be used for assay calibration or as an absolute reference material.




















## LIMITATIONS

These products are unassayed control materials. They must be used in accordance with local, state, and/or federal regulations or accreditation requirements, as applicable. 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 these products with their chosen instrumentation, hydration method, 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

These products were prepared using suitable inactivation methods. While these products have been tested for innocuity, universal laboratory precautions are recommended, and materials should be treated as though viable.

## KEY OF SYMBOLS

	Authorized Representative in the European Community		Health Hazard
	Batch Code (Lot)		In Vitro Diagnostic Medical Device
	Biological Risks		Manufacturer
	Catalog Number		Negative Control
	Caution		Positive Control
	CE Mark		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		

*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 these products allow the purchaser to use them for 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.

The Microbiologics logo and Helix Elite™ are registered trademarks of Microbiologics, Inc.

## WEBSITE

Visit our website, [www.microbiologics.com](http://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](http://www.microbiologics.com)

### Customer Service

Tel: +1.320.253.7400  
U.S. Toll Free: +1.800.599.2847  
Email: [info@microbiologics.com](mailto:info@microbiologics.com)

### Technical Support

Tel: +1.320.229.7045  
U.S. Toll Free: +1.866.286.6691  
Email: [techsupport@microbiologics.com](mailto:techsupport@microbiologics.com)



### Medimark® Europe

11, rue Emile Zola B.P. 2332  
38033 Grenoble Cedex 2, France  
Tel: 33 (0)4 76 86 43 22  
Fax: 33(0)4 76 17 19 82  
Email: [info@medimark-europe.com](mailto:info@medimark-europe.com)


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

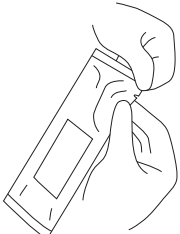
The Rapid Group B Streptococcus (GBS) Verification Panel consists of 10 individually packaged lyophilized positive control swabs and 10 individually packaged lyophilized negative control swabs. The Rapid Group B Streptococcus (GBS) Control Panel consists of 6 individually packaged lyophilized positive control swabs and 6 individually packaged lyophilized negative control swabs.

**1**



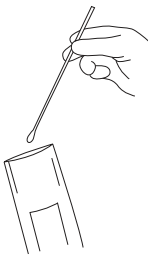
Read package insert, instructions for use or laboratory protocol for the applicable assay. Some instruments and assays are equipped with special QC settings. In these instances, it may be necessary to use the special setting when using QC sets and panels.

**2**



Tear open pouch at notch.

**3**

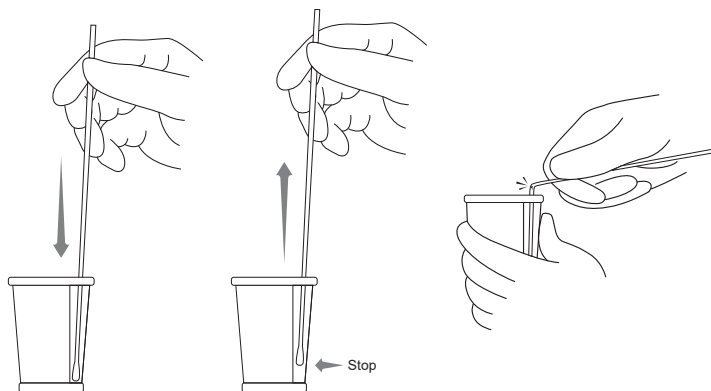


Remove swab from pouch.

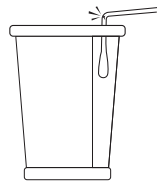
**4**

Insert the swab as instructed by the assay manufacturer.

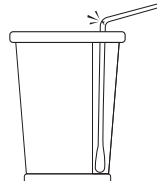
If protocol instructs to break the swab, insert the swab into the device, lift the swab up slightly from the bottom of the device and break/snap the swab to the right by pushing the shaft of the swab against the opening of the device. The break point should be appropriate to the size of the test device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



Stop



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.

**5**

Process following assay instructions for use.

## REVISION HISTORY ---

Publication History		
Revision	Date	Description of Change
A	2022-03-30	Initial release
B	2022-04-08	Revised bullet #2 statement in Warning and Precautions section. Added statement in Limitations section.
C	2022-06-22	Update verbiage in 4a for clearer breaking instructions. Revised 4a image. Added *** to Table 1. Added statement to Warnings and Precautions.