

Supplemental Information



#8227 *C. difficile* Control Panel (Inactivated Swab)

INTENDED USE

Helix Elite™ Molecular Standards (Inactivated Swab) and QC Sets and Panels - Helix Elite™ Molecular Standards (Inactivated Swab) are intended for use as external controls for qualitative detection by molecular assays.

The *C. difficile* Control Panel (Inactivated Swab) is intended for use as an external positive quality control material to monitor the performance of in vitro laboratory nucleic acid testing procedures for the qualitative detection of *Clostridioides difficile* and *Clostridium sordellii*. The controls comprise of cultured and inactivated *Clostridioides difficile* and *Clostridium sordellii*.

SUMMARY AND EXPLANATION

The *C. difficile* Control Panel (Inactivated Swab) is a ready-to-use external quality control that can be used to monitor the extraction, amplification and detection of molecular assay or instruments. Routine use of quality controls helps in identifying problems with the test system due to instrument or reagent failure. At a minimum, controls should be run at the frequency recommended by the assay system manufacturer.

These independent controls may also be used in evaluation of laboratory proficiency and training, or determination of the lot-to-lot consistency of assay consumables as directed by various regulatory requirements and standards.

PRINCIPLES

The *C. difficile* Control Panel (Inactivated Swab) is comprised of cultured organisms inactivated by chemical, radiological, or heat treatments. Each swab is packaged in a single-use foil pouch. Users should follow assay manufacturer or laboratory procedures for processing controls.

COMPOSITION

Each *C. difficile* Control Panel (Inactivated Swab) consists of individually packaged control material that contain inactivated pathogen(s) stabilized in a proprietary matrix of excipients.

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.
- Do not open foil pouch until ready to use.
- This product must be treated as a viable specimen and handled in accordance with Biosafety Level 2 practices as described in the United States Department of Health and Human Services Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH), Biosafety in Microbiological and Biomedical Laboratories, or other equivalent guidelines.
- Wear proper personal protective equipment.

- 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.
- These products do not contain any hazardous substances listed in 67/548/EEC or listed in 1272/2008/EC.
- These products are not made with natural rubber latex.
- Not all instruments and assays are compatible with multi-target controls. Customer is responsible for ensuring compatibility of the control with the assay or protocol in use.

MATERIALS REQUIRED BUT NOT PROVIDED

- Nucleic acid extraction kit and assay
- Instrumentation for detection
- Vortex
- Sample Reagent Tube

INSTRUCTIONS FOR USE

Preparation

1. Read assay package insert, instructions for use, or applicable lab protocol. 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.

Hydration and Use

1. Rehydrate the lyophilized swab by adding it to sample reagent tube with 2.0 ml of hydrating fluid. Break the swab by snapping the shaft on the rim of the sample reagent tube
2. Vortex or vigorously shake for a full 10 seconds.
3. Use the transfer pipette provided in the assay to transfer the entire volume of suspension to the assay cartridge
4. Suspension must be used within 5 hours of mixing

STORAGE AND EXPIRATION

Store the *C. difficile* Control Panel (Inactivated Swab) at 2°C - 25°C in the original packaging up to the indicated expiration date. After opening the foil pouch use the pellet immediately.

C. difficile Control Panel (Inactivated Swab) should not be used if:

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

LIMITATIONS

This product may not be suitable for use with all kits and procedures. Only primers and probes that hybridize to sequences of the extracted nucleic acids of the organism should be expected to yield a positive reaction.

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



Batch Code (Lot)



Catalog Number



Caution, Consult Accompanying Documents



Contains sufficient for <n> tests



In Vitro Medical Device



Authorized Representative in the European Community



Manufacturer



Temperature Limitation



Use By



Refer to Instructions for Use



Telephone Number



CE Mark

PRODUCT WARRANTY

- These products are warranted 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
 - **For information regarding inhibitory substances, refer to the catalog number's product page at www.microbiologics.com or to the *QC Sets and Panels: Technical Information* document at www.microbiologics.com, or**
 - **Contact Technical Support at 320.229.7045, U.S. Toll Free 1.866.286.6691, or techsupport@microbiologics.com**

WEBSITE

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

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