

INSTRUCTIONS FOR USE

IVD

■ Assayed *C. difficile*/Epi Control Panel

INTENDED USE

The Assayed *C. difficile*/Epi Control Panel is intended for use as external assayed positive and negative quality controls to monitor the performance of in vitro laboratory nucleic acid testing procedures for the qualitative detection of *Clostridioides (Clostridium) difficile* performed with the Cepheid Xpert® *C. difficile*/Epi assay on the GeneXpert® Dx System. The controls comprise cultured and inactivated *Clostridioides (Clostridium) difficile* 027-NAP1-B1 as the positive control and *Clostridium sordellii* as the negative control.

The Assayed *C. difficile*/Epi Control Panel is not intended to replace manufacturer controls provided with the device.

SUMMARY AND EXPLANATION

The Assayed *C. difficile*/Epi Control Panel is a ready-to-use external quality control that can be used to monitor the extraction, amplification and detection of the Cepheid Xpert® *C. difficile*/Epi assay. 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.

PRINCIPLE

Inactivated Assayed *C. difficile*/Epi Control Panel is comprised of cultured microorganisms which have been inactivated by heat treatments. The positive control contains an isolate of *Clostridioides difficile* which is detected by the assay. The negative control, *Clostridium sordelli*, is typically part of the microflora of the sample collected.

COMPOSITION

Each Assayed *C. difficile*/Epi Control Panel consists of 6 individually packaged positive control swabs. Each positive control swab contains a cultured and inactivated 027-NAP1-B1 strain of *Clostridioides difficile* at a target level that is designed to provide reproducible performance above the limit of detection of the Cepheid Xpert® *C. difficile*/Epi assay. The positive control swab is expected to produce positive results for each of the genes targeted by the Cepheid Xpert® *C. difficile*/Epi assay: toxin B (*tcdB*), binary toxin (CDT) and the variant regulator gene, *tcdC*. The kit also includes 6 individually packaged negative controls swabs of cultured and inactivated *Clostridium sordellii*. The organisms are prepared in a buffered solution with materials of plant and animal origin, preservatives and stabilizers. The suspension is lyophilized into a ready-to-use swab.

Clostridioides difficile was previously named *Clostridium difficile* as it is widely known.

WARNINGS AND PRECAUTIONS

- For In Vitro Diagnostic use only.
- Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- Not to be used by untrained personnel.
- 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 +1.320.229.7045 or U.S. Toll Free +1.866.286.6691.
- These products are not made with natural rubber latex.

STORAGE AND EXPIRATION

Store the Assayed *C. difficile*/Epi Control Panel at 2°C - 25°C in the original packaging up to the indicated expiration date. After opening the foil pouch, use the swab immediately and within 5 hours of addition to the Sample Reagent.

Inactivated Assayed *C. difficile*/Epi Control Panel should not be used if:

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

MATERIALS REQUIRED BUT NOT PROVIDED

- GeneXpert® Dx System
- Cepheid Xpert® *C. difficile*/Epi Assay kit
- Disposable Transfer Pipettes
- Package Insert of the Cepheid Xpert® *C. difficile*/Epi Assay

INSTRUCTIONS FOR USE

1. Read the package insert specific to the Cepheid Xpert® *C. difficile*/Epi assay.
2. Tear open the foil pouch containing the quality control swab at the notch.
3. Remove the swab from the pouch.
4. Insert the swab into the Sample Reagent provided in the Cepheid Xpert® *C. difficile*/Epi kit. Break the swab by lifting the swab a few millimeters from the bottom of the tube and pushing against the rim to break it.
5. Cap the Sample Reagent and vortex for 10 seconds.
6. Open the lid of the Cepheid Xpert® *C. difficile*/Epi cartridge. Use a transfer pipette to transfer the entire contents of the Sample Reagent tube to the Cepheid Xpert® *C. difficile*/Epi Cartridge.
7. Close the cartridge lid and start the test. Test must be started within 30 minutes of adding the sample to the cartridge.

LIMITATIONS

- Quality control materials should be used in accordance with local, state, federal regulations, and accreditation requirements.
- Each positive and negative controls swab is only intended to be used once.

EXPECTED VALUES

The following results are expected when running the 8200 controls with the Cepheid Xpert® *C. difficile*/Epi assay:

8200 Control	Toxin B	Binary Toxin	<i>tcdC</i>	SPS	Interpretation
6039 – Positive Control	+	+	+	+/-	Toxigenic <i>C. diff</i> POSITIVE; 027-NAP1-B1 PRESUMPTIVE POSITIVE
6040 – Negative Control	-	-	-	+	Toxigenic <i>C. diff</i> NEGATIVE; 027-NAP1-B1 PRESUMPTIVE NEGATIVE

SPC: Sample Processing Control

A positive control that yields a negative result for any of the three analytes may be indicative of a specimen handling/preparation problem. Repeat the test using a new swab.

If a negative control yields a positive result, clean the GeneXpert® instrument per the user manual and clean the work area. Repeat the test using a new swab.

The performance of the Assayed *C. difficile*/Epi Control Panel was evaluated in a study that was performed using three different production lots, three test sites using three different GeneXpert® Dx Systems and six different users. The results of the study are summarized below.

Positive Analyte	Agreement (%) by Test Site/GeneXpert® System			
	Site 1	Site 2 ¹	Site 3	Overall
<i>Clostridioides difficile</i> (<i>tcdB</i> /binary toxin/ <i>tcdC</i>)	30/30 (100)	31/31 (100)	30/30 (100)	91/91 (100)

¹ One ERROR response was observed; a new control was retested and the expected results were obtained.

Negative Analyte	Agreement (%) by Test Site/GeneXpert® System			
	Site 1	Site 2 ¹	Site 3	Overall
<i>Clostridium sordellii</i>	30/30 (100)	31/31 (100)	30/30 (100)	91/91 (100)

¹ Two ERROR responses were observed; a new control was retested and the expected results were obtained.

Site	Mean Ct (%CV)			
	<i>tcdB</i>	Binary Toxin	<i>tcdC</i>	SPC ¹
1	29.5 (2.6)	29.0 (2.5)	28.8 (2.5)	32.7 (2.1)
2	29.7 (2.2)	29.2 (2.1)	29.1 (2.1)	32.3 (1.6)
3	29.3 (1.5)	28.7 (1.6)	28.6 (1.6)	32.5 (2.0)
All Sites	29.5 (2.2)	28.9 (2.2)	28.8 (2.2)	32.5 (2.0)

%CV: Percent Coefficient of Variation; SPC: Sample Processing Control

¹The values shown for the SPC are only for testing performed with Negative Controls

KEY OF SYMBOLS



Batch code (Lot)



In vitro diagnostic medical device



Catalog number



Manufacturer



Caution



Temperature limit



Consult instructions for use or consult electronic instructions for use



Use-by-date



Contains sufficient for <n> tests

Rx ONLY

Federal Law restricts this device to sale by or on the order of a licensed practitioner.

Please refer to product labels for applicable symbols.

PRODUCT WARRANTY

- These products are warranted to meet the specifications and performance printed and illustrated in the 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.

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.
- Issues regarding the performance of the Assayed C. difficile/Epi Control Panel should be addressed to Microbiologics, Inc. directly.
- The Microbiologics logo and Helix Elite™ are registered trademarks of Microbiologics, Inc.

WEBSITE

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

BIBLIOGRAPHY

1. Cepheid Xpert® C. difficile/Epi [product insert]. Cepheid, Sunnyvale, CA 94089 USA

ASSISTANCE



Microbiologics, Inc.

200 Cooper Avenue North
St. Cloud, MN 56303 USA
www.microbiologics.com

Technical Support

Tel: +1.320.229.7045
U.S. Toll Free: +1.866.286.6691
Email: techsupport@microbiologics.com

Customer Service

Tel: +1.320.253.7400
U.S. Toll Free: +1.800.599.2847
Email: info@microbiologics.com

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

ILLUSTRATED INSTRUCTIONS

1

Read the package insert specific to the Cepheid Xpert® C. difficile/Epi.

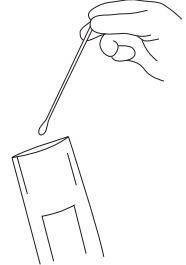
2

Tear open the foil pouch containing the quality control swab at the notch.



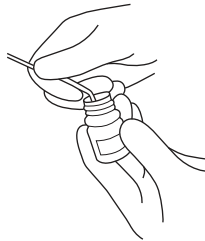
3

Remove the swab from the pouch.



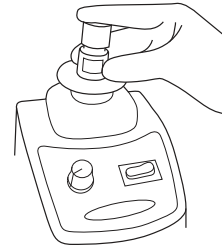
4

Insert the swab into the Sample Reagent provided in the Cepheid Xpert® C. difficile/Epi Kit. Break the swab by lifting the swab a few millimeters from the bottom of the tube and pushing against the rim to break it.



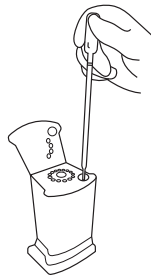
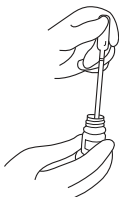
5

Cap the sample reagent and vortex for 10 seconds.



6

Open the lid of the Cepheid Xpert® C. difficile/Epi cartridge. Use a transfer pipette to transfer the entire contents of the Sample Reagent tube to the Cepheid Xpert® C. difficile/Epi Cartridge.



7

Close the cartridge lid and start the test. Test must be started within 30 minutes of adding the sample to the cartridge.

