

Xpert[®] C. difficile/Epi

*Testing
Protocol
In Brief*



Cepheid has discontinued the Xpert® C. difficile Assay

- Xpert® C. difficile/Epi is the replacement assay.
- This assay can detect the 027/NAP1/BI toxigenic strain for epidemiology purposes only.
- Sample processing is the same.
- External reporting is the same.
- Paste the link below in your browser for more detailed training information:

<https://cepheid.widen.net/s/7p5bzcclh2/cepheid-xpert-c-difficile-epi-technical-training-presentation-us-ivd-303-2933-english>

Stool Sample Recommended Size Card

Refer to the Instructions for Use for detailed instructions, precautions, and warnings.



- Xpert® C. difficile
- Xpert® C. difficile/Epi
- Xpert® Norovirus

1 Briefly place a swab in the unformed stool

2 Obtain the correct amount of sample on the swab. See photos for sample amount to use for the test.

Too little size sample



Correct size sample



Excessive size sample



Xpert® Cartridge Preparation Overview

Refer to the Instructions for Use for detailed instructions, precautions, and warnings.



- Xpert® MRSA NxG
- Xpert® MRSA/SA SSTI

- Xpert® vanA
- Xpert® *C. difficile*

- Xpert® *C. difficile*/Epi
- Xpert® SA Nasal Complete

- Xpert® Norovirus

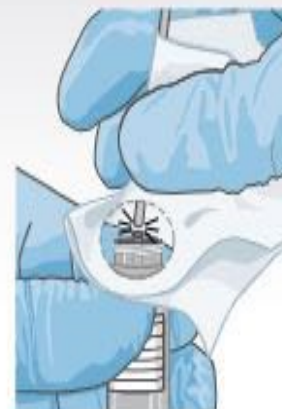
- 1** Obtain one cartridge and one Sample Reagent vial.



- 2** Insert the swab into the Sample Reagent vial. Use gauze to minimize risk of contamination.



- 3** Hold the swab above the score mark. Break the swab at the score mark.



- 4** Recap the Sample Reagent vial and vortex for 10 seconds.



- 5** Open the cartridge lid.



- 6** Aspirate all of the Sample Reagent vial contents with a disposable transfer pipette.



- 7** Empty the pipette into the sample chamber.



- 8** Close the cartridge lid. Start the test within the time-frame specified in the instructions for use.



Xpert® Retest Procedure

Refer to the Instructions for Use for detailed instructions, precautions, and warnings.



- Xpert® *C. difficile*
- Xpert® *C. difficile*/Epi
- Xpert® *vanA*
- Xpert® MRSA/SA SSTI

Follow this retest procedure within 3 hours of an **ERROR, INVALID, or NO RESULT**.

For retest after 3 hours of an indeterminate result, repeat the test with the remaining sample. Collect a new sample if the remaining volume is insufficient.

- 1** Retain the used cartridge. Obtain a new Xpert cartridge and a new Sample Reagent vial.



- 2** Transfer all the remaining contents from the Sample chamber of the used cartridge to a new Sample Reagent vial.



- 3** Recap the Sample Reagent vial and vortex for 10 seconds.



- 4** Open the new Xpert cartridge lid.



- 5** Aspirate all of the Sample Reagent vial contents with a disposable transfer pipette.



- 6** Empty the contents into the sample chamber of the new Xpert cartridge.



- 7** Close the cartridge lid. Start the test within the timeframe specified in the Instructions for Use.

