

Evaluation of Copan Fecal Swab® with Cepheid GeneXpert® technology for the detection of *C. difficile* in stools samples



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INTRODUCTION

Clostridium difficile (CD) is a Gram positive bacterium responsible of colon inflammations that can lead to diarrhea or pseudomembranous colitis.

CD is the major responsible of nosocomial infections, it usually affects older adults in hospitals and long term care facilities and typically occurs after a long antibiotic therapies. In the past years CD infections have become more frequent and more difficult to treat, so a prompt diagnosis is essential in order to reduce the spreading of the infection and avoid outbreaks.

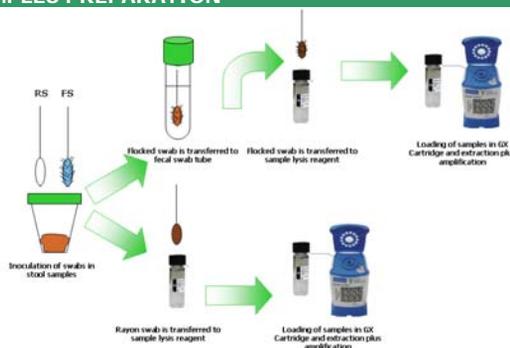
Xpert C. difficile® (Cepheid) is a revolutionary new molecular diagnostic test for on-demand identification and differentiation of Toxin B, Binary Toxin and tcdC deletion in less than one hour, from stool specimens from patients suspected of having *Clostridium difficile* infection (CDI). The test is also the first to identify patients most likely to have the emerging BI/NAP/027 strain — which has been associated with severe outbreaks of hospital-associated *C. difficile* in the U.S. and Europe.

Copan Fecal swab is a new collection and transport system for stool samples and provides a specimen that may be analyzed by culture, rapid kits and nucleic acids techniques. The product comprises of a tube containing 2 ml of modified Cary Blair medium and a flocked swab. After the specimen is collected, the flocked swab is broken into the tube with medium: the sampled material is released by the flocked swab into the medium after vortexing, resulting in an homogeneous specimen suspension suitable to run multiple assays.

Aim of this study is to compare:

- Copan Fecal Swab and traditional liquid medium transystem for its ability to be used in combination with Xpert C. difficile molecular test.

SAMPLES PREPARATION



RESULTS

In total, 48 samples were tested in this study:

38 samples gave a concordant result:

- 22 sample were found positive with both collection devices
- 16 samples were found negative with both collection devices

10 samples gave discordant results:

- 1 sample was found positive with flocked swab but unresolved with rayon swab: it was repeated with a second real time PCR method that confirmed it as positive.
- 6 samples were found invalid with one or the other device
- 3 samples were invalid with both collection device: after retesting one sample was still invalid, the other two were resolved as negative with fecal swab only. For the retesting of Fecal swab, 200 uL of Cary blair medium were added to the sample lysis reagent.

Positivity rate with fecal swab (FS): $23/48 = 47,9 \%$

Positivity rate with rayon swab (RS): $22/48 = 45,8 \%$

% invalid with RS – % invalid with FS = 5 %

MATERIALS

- Copan Fecal Swab: 470CE
- Copan liquid Stuart Transystem: Cepheid part number 900-0370
- Xpert C. difficile: CGXCDIFFICILE-CE-10
- GeneXpert® Platform: CGXIV-4N1-6



Copan Liq. Transystem:
Code 900-0370



Copan Fecal Swab:
Code 470CE



Xpert C. difficile: GXCDIFFICILE-CE-10
Cartridge and equipment

PROCEDURE

A total of 48 stool samples, collected from symptomatic patients in sterile containers, were used for this evaluation.

Samples were tested with Xpert C. difficile cartridge (Cepheid) in duplicate. Each single sample was first collected using the rayon swab (RS) from liquid Stuart transystem as suggested in the assay package insert, and subsequently the flocked swab (FS) from fecal swab has been used to collect the same fecal sample. After collection RS was immediately broken into the sample lysis reagent included in Xpert C.difficile test, while the FS was transferred into the Fecal swab tube containing the medium, vortexed and transferred in a second vial of sample lysis reagent. Both sample lysis reagent vials were vortexed for 10s and the entire volume of each vial was transferred in two different Xpert C. difficile cartridges. Samples were then processed as described in Xpert C. difficile package insert.

CONCLUSIONS

- There is no significant difference between the positivity rate obtained with Copan Fecal swab than Rayon swab, so Fecal Swab can be used in combination with Xpert C. difficile assay.
- There is a significant difference between the number of invalid results obtained with the two transport media.
- The Copan Fecal swab is compatible with the performance of the Xpert C. difficile assay with the advantage that additional testing can be done from the same sample
- Xpert C. difficile assay confirms to be a revolutionary, fast, easy and sensitive diagnostic tests for correct treatment and for disease control within the hospital environment.

TAKE HOME MESSAGE

Traditional stool specimens are transported in different sized containers without a medium to stabilize enteric microbes: this causes the necessity for large storing refrigeration space. Fecal specimens collected in Copan Fecal swab are transported in a medium that stabilizes enteric pathogens and can be used for culture, molecular biology, rapid antigen and toxin testing kits. The elution of the sample from flocked swab in the medium generates 2 ml of homogeneous original sample suspension in tubes with a standard size that can be stored in a more functional way. Moreover Copan Fecal swab can be used also for rectal collection.