

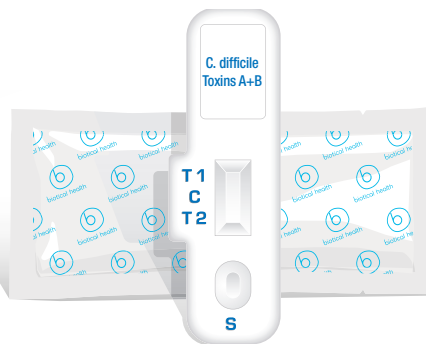
biotical health

IN VITRO DIAGNOSTIC DEVICES

ready to test

Clostridium difficile Toxins A+B Card

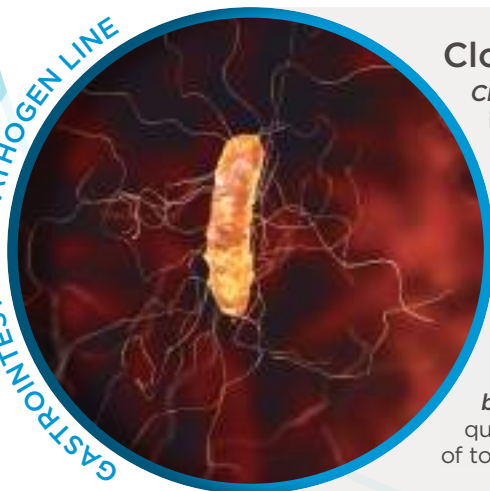
Rapid Test to detect
Clostridium difficile Toxins A+B
in stool samples



QUICK, ACCURATE AND EASY-TO-USE TEST

| biotical Clostridium difficile Toxin A+B vs Evaluation Criteria | Sensitivity | Specificity | PPV | NPV | Accuracy |
|---|--------------|-------------|--------------|-------------|----------------|
| Mean value (Toxin A) | 96.9% | 100% | 100% | 99.0% | 99.2% |
| Confidence interval 95% (Toxin A) | 92.2 - 99.9% | 96.2 - 100% | 87.7 - 100% | 94.4 - 100% | 95.66 - 99.98% |
| Mean value (Toxin B) | 100% | 98.9% | 97.3% | 100% | 99.2% |
| Confidence interval 95% (Toxin B) | 90.3 - 100% | 94.0 - 100% | 85.8 - 99.9% | 95.9 - 100% | 95.66 - 99.98% |

GASTROINTESTINAL PATHOGEN LINE



Clostridium difficile

Clostridium difficile (*C. difficile*) is a Gram-positive anaerobic bacterium. It is the main pathogen linked to diarrhea associated with antibiotics and/or pseudomembranous colitis in hospitalized patients, the main cause of diarrhea associated with healthcare in developed countries, and the main origin of morbidity and mortality of nosocomial disease around the world.

Most of the bacterial flora in the colon of a healthy adult is generally resistant to colonization by *C. difficile*. If the bacterial flora is altered (due to the excessive use of antibiotics, for example), resistance to colonization by this bacterium is lost and the microorganism is allowed to multiply in the colon. In addition, its ability to form spores allows this bacterium to persist in patients for long periods and facilitates fecal-oral transmission.

biotical Clostridium difficile Toxins A + B card is an immunochromatographic qualitative test, easy to use and with almost immediate results, for the detection of toxigenic strains of *Clostridium difficile* in stool samples.

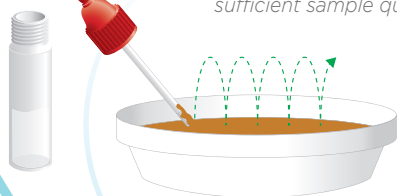
Ref.:
RTB25CD



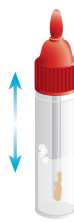
PRODUCT MANUFACTURED AND DEVELOPED IN SPAIN

C. difficile Toxins A + B card Test procedure

1 Take out the cap of the stool collection tube and use the stick to pick up sufficient sample quantity



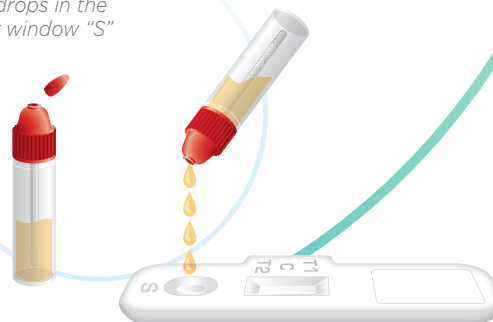
2



Close the tube with the diluent and stool sample. Shake the tube in order to assure good sample dispersion.

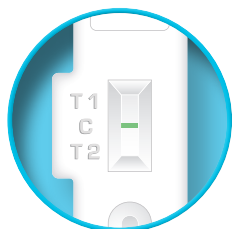
3

Add 4 drops in the circular window "S"

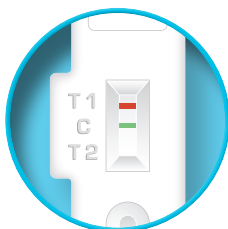


10'

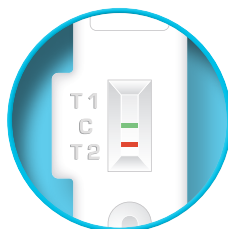
Read the results after 10 minutes



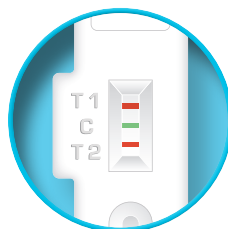
NEGATIVE



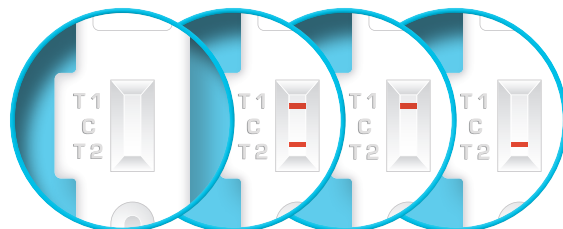
**POSITIVE TOXIN A
NEGATIVE TOXIN B**



**NEGATIVE TOXIN A
POSITIVE TOXIN B**



**POSITIVE TOXIN A
POSITIVE TOXIN B**



INVALID RESULTS



**biotical Clostridium
difficile Toxins A+B kit**

Kit contents



Test card in sealed bag

25 pcs.



Stool collection tubes with diluent

25 pcs.

Positive Control can be included upon request