

RAPID C. DIFFICILE TOX A&B

QUALITATIVE RAPID IMMUNOCHROMATOGRAPHIC ASSAY



DIAMONDIAL
Diagnostic Mondial Laboratories

- Qualitative rapid immunochromatographic assay
- Detection of Clostridium difficile toxin A & B antigens in stool specimens
- High degree of sensitivity and specificity



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DiaMondial C. difficile Tox A&B Rapid Tests

THE DIAMONDIAL RAPID C. DIFFICILE TOX A&B IS A QUALITATIVE RAPID IMMUNOCHROMATOGRAPHIC ASSAY FOR DETECTION OF CLOSTRIDIUM DIFFICILE ANTIGENS IN STOOL SPECIMENS. THE METHOD EMPLOYS A UNIQUE COMBINATION OF MONOCLONAL DYE CONJUGATE AND POLYCLONAL SOLID PHASE ANTIBODIES TO SELECTIVELY IDENTIFY C. DIFFICILE TOX A&B ANTIGENS WITH A HIGH DEGREE OF SENSITIVITY AND SPECIFICITY.



SUMMARY AND EXPLANATION

Clostridium difficile is a major cause of antibiotic-associated diarrhea and pseudomembranous colitis. It is now one of the most commonly detected pathogens and an important cause of nosocomial infections in hospitals and nursing homes. The organism has been isolated from diverse natural habitats, including soils, hay, sand, dung from various large mammals (cows, donkeys and horses), dog, cat, rodent and from human feces. C. difficile produces at least three potential virulence factors among them Toxin A and Toxin B are thought to be the most important in the pathogenesis of C. difficile associated diseases.

Toxin A is an enterotoxin which seems to interfere with the cytoskeleton of the intestinal epithelial cells, rendering them non functional while Toxin B is a cytotoxin that induces strong cytopathic effects in tissue cultures cell lines.

Since not all strains of C. difficile produce toxins and approx. 2% of healthy adults as well as up to 50% of children younger than 2 years can be colonized with C. difficile, the detection of the toxins (Toxin A and Toxin B) in stool samples of patients with diarrhea is more significant than culturing the bacteria.

PRINCIPLE OF THE TEST

The Rapid C. difficile TOX A&B is a lateral flow, rapid immunochromatographic test that detects C. difficile in human faeces.

The test device consists of a plastic housing containing two different strips for the detection of C. difficile Toxin A or C. difficile Toxin B. A colored anti C. difficile Toxin A or anti C. difficile Toxin B monoclonal antibody conjugate to colloidal gold is placed at the left end of the membrane.

After collection in a tube containing the extraction solution, the faeces sample is dissolved and few drops of this extract are added into each well of the reaction device.

As the test sample flows through the absorbent device, the labeled antibody will bind to the Toxin A or Toxin B antigen (when present in the sample) forming an antibody antigen complex.

In the Test zone, this complex binds to the polyclonal anti-Toxin A or anti-Toxin B antibody inducing a pink line.

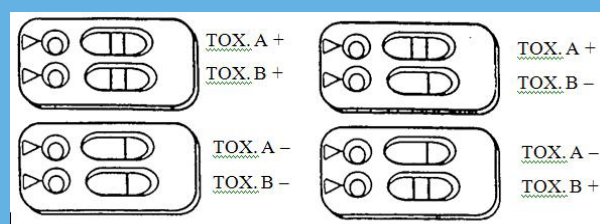
In the absence of Toxin A or Toxin B, there is no line in the positive reaction zone. The reaction mixture continues flowing through the absorbent device. Unbound conjugate binds to the reagent in the Control zone producing a pink line proving that the reagents are working correctly.

COMPOSITION OF THE KIT:

- 20 devices of Rapid C. difficile TOX A&B test
- 20 disposable plastic droppers
- 20 vials of 2 mL of extraction solution
- 1 vial with lyophilized Rapid C. difficile TOX A&B Positive Control

Product	Code	Content
Rapid C. difficile TOX A&B	DM-DML 6500	20 Tests

INTERPRETATION OF RESULTS



Negative

Only one colored line appears in the control zone. No line is visible in the test zone.

Positive

In addition to the control line, a clearly distinguishable line also appears in the test zone.

Inconclusive

If there is no distinct colored line visible in the test and control zone, then the test is inconclusive. Repeat the test.

Positive Control

A clearly distinguishable line should appear in the test zones and control zones.