AG- CLOSTRIDIUM DEFFICLE TOXIN A/B RAPID TEST KIT

INSTRUCTIONS FOR USE

AstraGene Clostridium Defficle Toxin A/B rapid test kit is a rapid chromatographic immunoassay for the qualitative detection of Clostridium difficile Toxin A and Toxin B in the human feces specimen.

PRINCIPLE

AstraGene Clostridium Defficle Toxin A/B rapid test kit detects two distinct antigens in fecal specimens for C. difficile, viz., Toxin A and Toxin B on two different test strips in a single test device, thus simultaneously detecting two antigens specific to Clostridium difficile.

For C.difficile-specific Toxin A Testing :The membrane is precoated with anti-C.diff Toxin A antibody and anti-C.diff Toxin A antibody on the test line region. During testing, the specimen reacts with the particle coated with anti-C.diff Toxin A antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-C.diff Toxin A antibody on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

For C.difficile-specifc Toxin B Testing :The membrane is precoated with anti-C.diff Toxin B antibody and anti-C.diff Toxin B antibody on the test line region. During testing, the specimen reacts with the particle coated with anti-C.diff Toxin B antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-C.diff Toxin B antibody on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

PACKAGE CONTENTS

Description	**10 tests**	1 test
Test Cassette and Desiccant	10	1
Specimen Collection tube with buffer	10	1
IFU	1	1

Catalogue Number	**10 tests**	**1 test**
Cassette Model	AG/RTK/CDT/24/01	AG/RTK/CDT/24/02

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Clock or timer.
- Stool container
- Centrifuge
- Pipette
- Latex gloves

STORAGE &STABILITY

- The test device in the sealed pouch should be stored at 2-30ºC up to the expiration date. Do not freeze the test device.
- The Fecal Specimen Collection Device containing the buffer should be stored at 2-30ºC.
- The test device should be kept away from direct sunlight, moisture and heat. and heat.

SPECIMEN COLLECTION & PREPARATION

- The stool specimens must be tested as soon as possible after collection. If necessary, original feces specimen may be stored at 2-8°C for 3 days or -20°C for longer periods of time; extracted specimen in buffer may be stored at 2-8°C for 1 week or -20°C for longer periods of time.
- Make sure that the specimens are not treated with solutions containing formaldehyde or its derivatives.

PROCEDURE

Allow the test, specimen, collection buffer and/or control to equilibrate to room temperature (15-30°C) prior to testing.

To collect fecal specimens:

- Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain enough antigens (if present). Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours. For long term storage, specimens should be kept below -20°C.

  To process fecal specimens:

  For Solid Specimens: Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the fecal specimen at least 3 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.

  For Liquid Specimens: Hold the dropper vertically, aspirate fecal specimens, and then transfer 2 drops of the liquid specimen (approximately 80 µL) into the specimen collection tube containing the extraction buffer. Tighten the cap onto the specimen collection tube, and then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Leave the collection tube for reaction for 2 minutes.
- Bring the pouch to room temperature before opening it. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
- Hold the specimen collection tube upright and unscrew the tip of the specimen collection tube. Invert the specimen collection tube and transfer 3 full drops of the extracted specimen (approximately 120 µL) to each of the specimen well (S) of the test devices, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
- Read the results at 10 minutes after dispensing the specimen. Do not read results after 20 minutes.
- Note: If the specimen does not migrate (presence of particles), centrifuge the diluted sample contained in the extraction buffer vial. Collect 120 µL of supernatant, dispense into the specimen well (S). Start the timer and continue from step 5 onwards in the above instructions for use.

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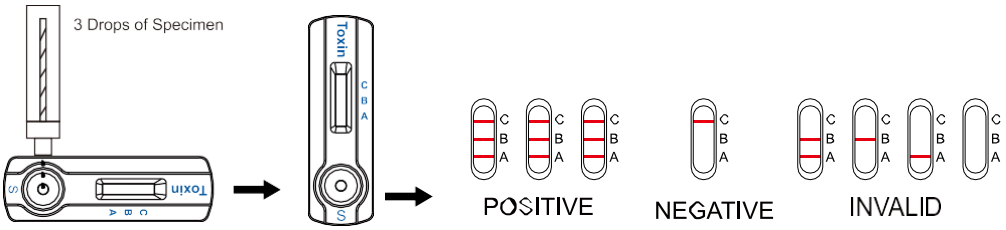

RESULT INTERPRETATIONS

The test results appear in two different test windows respectively for Toxin A or Toxin B. The interpretation criteria remain the same for positivity or negativity for specific antigens under tests as per indication of the respective Test window. The results are to be interpreted as follows:

Negative
A coloured band appears only at the control region (C), indicating a negative result.

Toxin A Positive
A clear control band (C) and a detectable test band (A) appear, indicating a positive result for Toxin A.

Toxin B Positive
A clear control band (C) and a detectable test band (B) appear, indicating a positive result for Toxin A.

Invalid
No visible band at the control region (C). Repeat with a new test device. If the test still fails, please contact the distributor with the lot number.

SPECIFICITY AND SENSITIVITY

Clostridium difficile Toxin A Results: Relative Sensitivity: 100%; Relative Specificity: 98.6%; Accuracy: 99.1%.
Clostridium difficile Toxin B Results: Relative Sensitivity: 100%; Relative Specificity: 98.6%; Accuracy: 99.1%.

LIMITATION OF THE PROCEDURE

- AstraGene Clostridium Defficile Toxin A/B rapid test kit is for in vitro diagnostic use only.
- The test is qualitative and cannot predict the quantity of antigens present in the sample. Clinical presentation and other test results must be taken into consideration to establish diagnosis.
- A positive test does not rule out the possibility that other pathogens may be present

WARNING AND PRECAUTION

- For professional in vitro diagnostic use only. Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

SYMBOLS

Do not use if package is damaged Manufacturer LOT Batch Code

CE mark of Conformity Refer to the instructions ISO 13485:2016 ISO GMP

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