

Instructions for Use

Version: 1.0.2
Revision date: 19-Dec-23

Human Clostridium difficile Toxin A/B Rapid Test Kit

Catalog No.: abx472011

Size: 40 tests

Storage: Store all reagents at 2-30°C. Keep dry. Avoid freezing

Application: For qualitative detection of Human Clostridium difficile Toxin A/B in human fecal samples.

Introduction and assay principle

Abbexa's Human Clostridium difficile Toxin A/B Rapid Test Kit is based on the gold immunochromatography assay (GICA) principle. Any Human Clostridium difficile Toxin A/B antigen present in the samples combines with the colloidal gold particle-labelled Human Clostridium difficile Toxin A/B antibody. When the concentration of Human Clostridium difficile Toxin A/B in the sample is more than the detection limit, there is a color change in the detection line and the result is positive. When the concentration of Human Clostridium difficile Toxin A/B in the sample solution is less than the detection limit, there is no color change in the detection line and the result is negative.

Kit Components (40 tests)

- Test cassettes: 40
- Extraction tube with buffer and applicator swab: 40

Material Required But Not Provided

- Pipette
- Timer

Sample preparation

- **Feces:** Take a sample from human stool using the applicator swab provided with the extraction buffer. When collecting a sample, insert the swab into 5 different sites of the feces to collect a total of approximately 50 mg of feces. Immediately insert the swab into the extraction tube. Shake to ensure the sample is fully mixed with the buffer. Allow the mixture to stand. Best results will be obtained if the assay is performed within 6 hours of sample collection. For liquid specimens, hold the pipette vertically and aspirate the fecal sample. Transfer 3 drops (approximately 80 µl) into the extraction tube. Shake to ensure the sample is fully mixed with the buffer. Samples can be stored for up to 6 months at -20°C if not tested within 1 hour after preparation.

Assay procedure

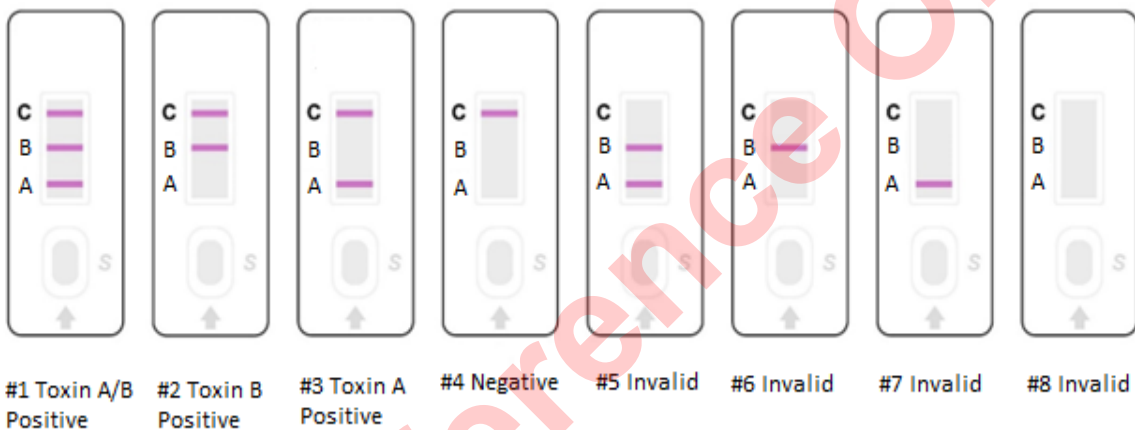
1. Bring all kit components and samples to room temperature.
2. Take a test cassette and lay it flat on a clean table. Using the extraction tube as a dropper bottle, slowly and vertically add 3 drops (approximately 90 µl) of diluted sample to the sample well on the test cassette. Avoid foaming.
3. Leave at room temperature for 10 min, then analyze the result.

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Results analysis

- **Toxin A and B Positive result:** A colored line is observed in the control (C) section and both test sections (A and B).
- **Toxin B Positive result, Toxin A Negative result:** A colored line is observed in the control (C) section and the first test section (B) but not the second test section (A).
- **Toxin A Positive result, Toxin B Negative result:** A colored line is observed in the control (C) section and the second test section (A) but not the first test section (B).
- **Toxin A and B Negative result:** A colored line is observed in the control (C) section but not in the test sections (A and B).
- **Invalid result:** No colored line is observed in the control (C) section.



Notes

1. The test cassettes should be brought to room temperature before use.
2. After opening the aluminum foil, use the test cassette as soon as possible.
3. Samples should be clear with no visible particles, turbidity or bacterial pollution.
4. Do not mix or re-use the disposable pipettes to avoid cross-contamination.
5. Avoid touching the cassette membrane through the sample well or test result window.
6. This kit is for qualitative detection of Human Clostridium difficile Toxin A/B in human fecal samples. For other sample types, a preliminary experiment is recommended to determine compatibility with this kit. Positive samples can be tested with another method (e.g. HPLC, LC/MS) for quantitative results.
7. This kit is for research use only and the results are for reference only. It is recommended to use this kit in conjunction with another detection method.
8. All waste should be disposed appropriately. Please note that you may need to follow special waste disposal procedures for infectious samples. Please check local disposal regulations.