C. difficile Toxin A/B+GDH Rapid Test Package Insert

INTENDED USE

The VivaDiag™ C. difficile Toxin A/B+GDH Rapid Test Device (Feces) is a rapid chromatographic immunoassay for the qualitative detection of Clostridium difficile Toxin A and Toxin B (C. difficile Toxins A&B), as well as Clostridium difficile glutamate dehydrogenase (C. difficile GDH)in human faecal specimens. The test is intended for use as an aid in the diagnosis of Clostridium difficile infection and designed for professional use only.

SUMMARY

Clostridium difficile (C. difficile) is an anaerobic gram-positive, spore-forming bacterium. The ability of C. difficile to form spores is the key feature which enables this bacterium to survive in patients and the physical environment for long periods, thereby facilitating its transmission. C. difficile is transmitted by the faecal-oral route. C. difficile is the principal pathogen related to antibiotic related diarrhoea and/or pseudomembranous colitis in hospitalised patients. Mature colonic bacterial flora in a healthy adult is generally resistant to C. difficile colonisation. However, if the normal enteric flora is altered, resistance to colonisation is lost. Any factor associated with the alteration of the normal enteric flora increases the risk of C. difficile colonisation after exposure to antibiotics, especially those with broad-spectrum activity such as penicillins, cephalo□sporins and clindamycin. C. difficile releases two high-molecular-weight toxins: toxins A and B, which are responsible for the clinical manifestations ranging from mild, self-limiting, watery diarrhoea to fulminant pseudomembranous colitis, toxic megacolon and death. Clostridium difficile glutamate dehydrogenase (C. difficile GDH) is an enzyme produced in large quantities by all toxigenic and non-toxigenic strains, making it an excellent biomarker.

PRINCIPLE

C. difficile GDH Rapid Test has one line of Anti-C.difficile GDH antibody on the detection line (T line) and one quality control line (C line). When extracted specimen is added to the specimen well, it will react with the labeled antibody to form a complex, the mixture then migrates through the membrane by capillary action and interacts with the coated Anti-C.difficile GDH antibody on the detection line. If the specimen contains C.difficile GDH antigen, the detection line will appear red indicating the C.difficile GDH antigen is positive. Otherwise, the test result will be negative. The test device also contains a quality control line C which should appear red for all valid tests. If the quality control line C does not appear, the test result will be invalid even if the detection line appears.

C. difficile Toxin A/B Rapid Test has one line of anti- C. difficile Toxin A antibody on the detection line (A line), one line of anti- C. difficile Toxin B antibody on the detection line (B line) and one quality control line (C line). When the specimen is added to the specimen well, it will react with the labeled antibody to form a complex; the mixture then migrates through the membrane by capillary action and interacts with the coated anti- C. difficile Toxin A antibody and C. difficile Toxin B antibody on the detection line. If the specimen contains C. difficile Toxin A or C. difficile Toxin B antigen, the detection line will appear red indicating the presence of C. difficile Toxin A or C. difficile Toxin B antigen. Otherwise, the test result will be negative. The test device also contains the quality control line C which should appear red for all valid tests. If the quality control line C does not appear, the test result will be invalid even if the detection line appears.

COMPOSITION

- Each test kit contains test devices, tubes with buffer.
- package insert

Materials required but not provided: timer,specimen collection container

STORAGE AND HANDLING

- Store the test kit in a cool, dry place between 2-30°C (36-86°F). Keep away from light. Exposure to temperature and/or humidity outside the specified conditions may cause inaccurate results.
- Use the test kits at temperatures between 15-30°C (59-86°F).
- Use the test kits between 10-90% humidity.
- The test device should be used within 60 minutes after removed from foil pouch.
- Do not freeze.

***Note:** All expiration dates are printed in Year-Month-Day format. 2022-06-18 indicates June 18, 2022.*

WARNINGS, PRECAUTIONS

- For in-vitro diagnostic use only.
- Do not use the test beyond the expiration date indicated on the package.
- Do not open the foil pouch of the test device exposing it to the ambient environment until the test device is ready for immediate use.
- Do not use the test if the foil pouch is damaged.
- Do not reuse test.
- All parts of kit are considered biohazardous after used and can potentially transmit infectious diseases from blood borne pathogens, even after you have performed cleaning and disinfection. Dispose of all samples and reagents used in the test procedure into a biohazard waste container and follow both of proper precautions and all local regulations.
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire package insert carefully prior to testing.
- Laboratory and healthcare professionals shall wear personal protective equipment such as laboratory coat, respirator, disposable gloves and eye protection during specimen collection, performing tests, and disposing of specimens and used test devices according to local regulation requirement.
- Humidity and temperature can adversely affect test results.
- Used testing materials should be discarded according to local regulations.

SPECIMEN COLLECTION AND HANDLING

The VivaDiag™ C. difficile Toxin A/B+GDH Test is intended only for use with human faecal specimens.

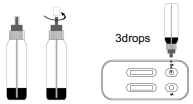
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods of time. Specimens can be stored at 2-8°C for up to 72 hours.
- Frozen samples should be completely thawed and brought to room temperature before testing. Avoid repeated freeze-thaw cycles.
- Pack specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.
- Patients with hemorrhoids, hematochezia and other symptoms should not be collected samples.
- Collect a random sample of feces in a clean dry container or receptacle.
- Collect random sample by using the applicator stick. Take sample from various surfaces of the feces specimen from 6 points.

- Re-insert the applicator stick into the tube and screw the cap tightly. Be careful not to break the tip of the Sample Collection Tube.

TEST PROCEDURE

Allow the Test Device and Extraction Solution to equilibrate to 15-30°C prior to testing.

1. Specimen collection and pre-treatment:
   1) Unscrew and remove the dilution tube applicator. Be careful not to spill or spatter solution from the tube. Collect specimens by inserting the applicator stick into at least 6 different sites of the feces.
   2) Place the applicator back into the tube and screw the cap tightly. Be careful not to break the tip of the dilution tube.
   3) Shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Specimens prepared in the specimen collection tube may be stored for 1 week at 2-8°C if not tested within 1 hour after preparation.
2. Testing
   1) Remove the test from its sealed pouch, and place it on a clean, level surface. To obtain a best result, the assay should be performed within one hour.
   2) Remove the tip of the dilution tube. Hold the tube vertically and dispense 3 drops of solution into the sample well of the Test Device.
   3) Avoid trapping air bubbles onto the sample pad, and do not drop any solution in observation window.
   As the test begins to work, you will see color move across the membrane.
3. The result should be read after 10 minutes. Do not interpret the result after more than 20 minutes.

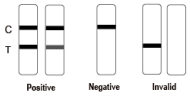


Note:

- *Do not interchange or mix extraction solution from different lots.*
- *Handle extraction solution with caution, do not contact with eyes or skin. If spilled on eyes or skin, wash thoroughly with water.*
- *Please follow local regulations to handle the used materials.*

INTERPRETATION OF TEST RESULTS

For C. difficile GDH:

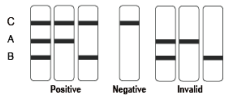


Positive*: Two distinct colored lines appear. One line should be in the control line region (C) and another line should be in the test line region (T).

Negative: One colored line appears in the control line region (C). No apparent colored line appears in the test line region (T).

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

For C. difficile Toxin A/ C. difficile Toxin B:



Positive*:

- **C. difficile Toxin A and C. difficile Toxin B Positive:** Three distinct colored lines appear. One line should be in the control line region (C) and two lines should be in the test line region (T1 and T2).
- **C. difficile Toxin A Positive:** Two distinct colored lines appear. One line should be in the control line region (C) and another line should be in the test line region (T1).
- **C. difficile Toxin B Positive:** Two distinct colored lines appear. One line should be in the control line region (C) and another line should be in the test line region (T2).

Negative: One red line appears in the control region(C). No apparent red or pink line appears in the test region (T).

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Note: *The intensity of the color in the test line region (T) may vary depending on the concentration of C. difficile Toxin A/B+GDH antigens present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.*

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is the internal procedural control. This procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test device has been maintained. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

- The VivaDiag™ C. difficile Toxin A/B+GDH Test is for professional in-vitro diagnostic use only.
- The VivaDiag™ C. difficile Toxin A/B+GDH Test should only be used for the qualitative detection of C. difficile antigens. The quantitative value of C. difficile antigens cannot be determined using this qualitative test.
- As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
- A positive result does not exclude the presence of other pathogens.

CROSS-REACTIVITY AND INTERFERENCE

Cross-Reactivity

The potential cross-reactive substances indicated in the below were tested at 1×10^9 organisms/mL and showed negative results and no cross-reaction

Potential cross-reactive substances	Potential cross-reactive substances	Potential cross-reactive substances
Campylobacter spp.	E. coli O157:H7	Listeria monocytogenes
Helicobacter pylori	Shigella spp.	Staphilococcus aureus
Salmonella spp.	Yersinia spp.	Yersinia enterolitica

Interference Substances

The substances indicated in the below at the concentration specified did not interfere with the results

of the test when added to stool samples (positive and negative ones).

Interfering substance	Concentration in specimen	Interfering substance	Concentration in specimen
Racecadotril	5% (w/v)	Metronidazole	10%(w/v)
Cimetidine	10%(w/v)	Omeprazole	3% (w/v)
Loperamide	5% (w/v)	Ampicillin	15%(w/v)
Ibuprofen	20% (w/v)	Artificial sweetener	5% (w/v)
Acetylsalicylic Acid	30% (w/v)	Palmitic Acid	40% (w/v)
Mucin	5%(w/v)	Barium Sulfate	5% (w/v)
Ascorbic acid	200 mg/L	Uric acid	600 mg/L
Glucose	20,000 mg/L	Albumin	20,000 mg/L
Oxalic acid	600 mg/L	Caffeine	400 mg/L
Bilirubin	1,000 mg/L	Urea	2,0000 mg/L

REFERENCES

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INDEX OF SYMBOLS

	Consult instructions for use		Use by	Σ	Contains sufficient for <n> tests
IVD	For *in vitro* diagnostic use only	LOT	Lot number	REF	Catalog number
2°C 30°C	Storage temperature limitations		Manufacturer		Do not reuse
EC REP	Authorized Representative				

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CE
IVD

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