Atlas Medical CE

Clostridium difficile Ag (GDH) Strip
One Step C. difficile Ag (GDH) Test Strip

A rapid one step test for the qualitative detection of *Clostridium difficile* glutamate dehydrogenase antigen in human feces.

IVD *For professional in vitro diagnostic use only*

2 - 30°C Store at 2-30°C

Intended use

The C difficile Ag (GDH) Strip is a rapid chromatographic immunoassay for the qualitative detection of *Clostridium difficile glutamate dehydrogenase* antigen in human feces specimens to aid in the diagnosis of *Clostridium difficile*.

Synthesis

Clostridium difficile is an anaerobic gram-positive spore-forming bacillus. The key feature in enabling it to persist in patients and the physical environment for long periods and thereby facilitating its transmission is the ability of *C. difficile* to form spores. *C. difficile* is transmitted through the fecal-oral route.

Clostridium difficile is the principal pathogen related to antibiotic associated diarrhea and/or pseudomembranous colitis in hospitalized patients.

Mature colonic bacterial flora in a healthy adult is generally resistant to *C. difficile* colonization. However, if the normal colonic flora is altered, resistance to colonization is lost. Thus, any factor associated with alteration of the normal enteric flora increases the risk of *C. difficile* colonization after exposure to antibiotics, especially those with broad-spectrum activity such as penicillins, cephalosporins and clindamycin.

C. difficile can release two high-molecular-weight toxins, toxin A and toxin B, which are responsible for the clinical manifestations, which range from mild, self-limited watery diarrhea to fulminant pseudomembranous colitis, toxic megacolon, and death.

Clostridium difficile Glutamate Dehydrogenase (GDH) is an enzyme produced in large quantities by all toxigenic and non-toxigenic strains, making it an excellent marker for the organism.

PRINCIPLE

The C. difficile Ag (GDH) Strip is a qualitative immunoassay for the detection of GDH antigen in human feces samples. The membrane is pre-coated with antibodies against GDH (red line) antigens on the test line region. During testing, the sample reacts with the colored particles coated with anti-GDH antibodies which were pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. As the sample flows through the test membrane, the colored particles conjugate migrate. In the case of a positive result the specific antibodies present on the membrane will react with the conjugate and generate one red colored line. The mixture continues to move across the membrane to the immobilized antibody places in the control band region. A green colored band always appears in the control line (second line) and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

precautions

- For professional in vitro diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed pack until use.
- Do not use the test if the sealed pack is damaged.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test should be discarded in a proper biohazard container after testing.
- The test must be carried out within 2 hours after opening the sealed pack.

STORAGE AND STABILITY

Store as packaged in the sealed pack either at refrigerated or room temperature (2-30ºC/36-86ºF). The test is stable through the expiration date printed on the sealed pack. The test must remain in the sealed pack until use. Do not freeze.

MATERIALS

Materials provided

- C. difficile Ag (GDH) Strips
- Package insert .
- Buffer in extraction tube .

materials required but no provided

- Specimen collection container
- Disposable gloves
- Timer

SPECIMEN COLLECTION AND PREPARATION

Collect sufficient quantity of feces (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-8ºC/36-46.4ºF) for 7 days prior to testing. For longer storage the specimen must be kept frozen at –20ºC/-4ºF. In this case, the sample will be totally thawed, and brought to room temperature before testing.

PROCEDURES

To process the collected stool samples (see illustration 1):

Use a separate swab or stick, dropper and testing tube or vial for each sample. Dispense exactly 1mL of the buffer into a testing tube. Introduce the swab or stick in different parts of the fecal specimen to pick up the sample and put into the testing tube or vial in order to assure good sample dispersion. For liquid stool samples, aspirate the fecal specimen with a dropper and add approx. 125 µL into the testing tube or vial with buffer.

Test Procedure (see illustration 2)

Allow the tests, stool samples and buffer to reach room temperature (15-30ºC/59-86ºF) prior to testing. Do not open the sealed pack until ready to perform the assay.

1. Use GDH Strip as soon as possible when opening the tube.
2. Extract some liquid from the top side with a dropper and dispense 150µL into a testing tube.
3. Use a separate test strip for each sample. Leave the test strip to stand vertically taking care of not surpassing the limit of immersion indicated with the arrows. Leave it for 1-3 minutes and place in a flat surface. Start the timer.
4. Read the result at **10 minutes** after dispensing the sample.

Illustration 1

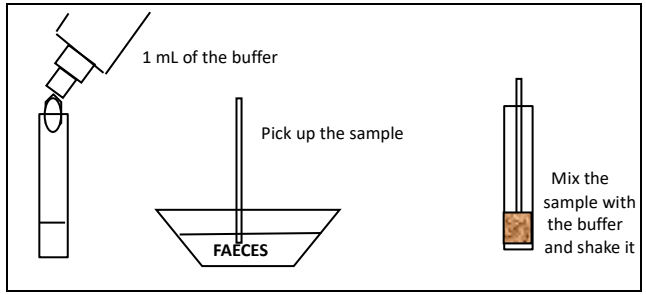
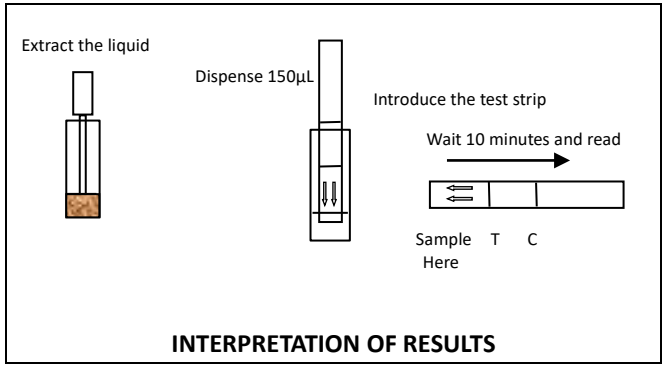


Illustration 2



INTERPRETATION OF RESULTS

Illustration 3

POSITIVE: Two lines appear across the central zone. A **red** line (marked in the illustration 3 with the letter T, test line) and a

green line (marked in the illustration 3 with the letter C, control line).

NEGATIVE: Only one **green** line (marked with the letter C in the illustration 3, control line) appears in the results zone.

INVALID: A total absence of the green control line regardless the appearance or not of the red test line. Note: Insufficient specimen volume, incorrect procedural techniques or deterioration of reagents 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 and contact your local distributor. See illustration 3.

Notes on the interpretation of results

The intensity of the red colored line (test line) in the results zone will vary depending on the concentration of GDH in the specimen. However, neither the quantitative value, nor the rate of increase in GDH can be determined by this qualitative test.

quality control

Internal procedural controls are included in the test:

- A green line (control line) appearing in the results zone. It confirms sufficient specimen volume and correct procedural technique.

limitations

1. C. difficile Ag (GDH) Strip test will only indicate the presence of *Clostridium difficile* in the specimen (qualitative detection) and should be used for the detection of *Clostridium difficile* in feces specimens only. Neither the quantitative value nor the rate of increase in antigen concentration can be determined by this test.
2. An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
3. Some stool samples can decrease the intensity of the control line.
4. The test must be carried out within 2 hours of opening the sealed pack.
5. This test provides a presumptive diagnosis of *Clostridium difficile* infection. A confirmed infection should only be made by a physician after all clinical and laboratory findings have been evaluated must be based in the correlation of the results with further clinical observations.
6. Positive results confirm the presence of *Clostridium difficile* GDH in fecal samples; nevertheless, it can be due to toxigenic or non-toxigenic strains of *Clostridium difficile*. A positive result should be followed up with additional laboratory techniques to determine the strain.

Expected values

Clostridium difficile is associated with 95-100% of cases of pseudomembranous colitis, 60-75% of cases of antibiotic-associated colitis and 35% of cases of antibiotic-associated diarrhea cases.

PERFORMANCE CHARACTERISTICS

SENSITIVITY AND SPECIFICITY

Some stool samples was studied from patients with diarrhea. The results showed using C. difficile Ag (GDH) Strip test in comparison with other commercial immunoassays test (IC test: *C. DIFF QUIK CHEK Complete*®TechLab***)*** were:
Sensitivity >99% and specificity >99%

CROSS-REACTIVITY

An evaluation was performed to determine the cross reactivity of C. difficile Ag *(*GDH) Strip test. There is not cross reactivity with common gastrointestinal microorganisms occasionally present in feces.

- *Campylobacter spp*	- *H. pylori*	- *Salmonella spp*
- *E. coli spp*	- *Shigella spp*	- *Yersinia spp*

REFERENCES

1. Wren, M.W.D, et al. “Laboratory diagnosis of *Clostridium difficile* infection. An evaluation of tests for faecal toxin, glutamate dehydrogenase, lactoferrin and toxigenic culture in the diagnostic laboratory”. British Journal of Biomedical Science, 66 (1), 2009

2. Vaishnavi, Ch., “Clinical spectrum & pathogenesis of *Clostridium difficile* associated diseases”. Indican J. Med. Res. 131, April 2010, pp 487-499

3. POUTANEN, S.M. et al. “*Clostridium difficile*-associated diarrhoea in adults”, CMAJ, 171(1) July 2004, pp. 51-58.

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REF	**Product Reference No.**	IVD	**For in-vitro diagnostic use.**
	Caution.		**Store at 2 - 30°C.**
	Read product insert before use.	Σ	**Number of tests in the pack.**
LOT	**Lot (batch) number.**		**Manufacturer.**
	Expiry date.		**Manufacturer telephone number.**
	Manufacturer fax number.		