Campylobacter Rapid Test Cassette (Feces) Package Insert

REF ICAM-602	English

A rapid test for the qualitative detection of Campylobacter in human feces.
For professional in vitro diagnostic use only.

INTENDED USE

The *Campylobacter* Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay for the qualitative detection of *Campylobacter* antigen in human feces specimen.

SUMMARY

Campylobacter enteritis is a food- and waterborne zoonotic illness and one of the most common causes of infectious diarrhea in the United States.[1,2] While identification of the etiological agent does not typically affect treatment outcomes, as the majority of these infections are self-limited, laboratory diagnosis is essential for epidemiological studies and outbreak tracking through strain identification and typing. Conventional laboratory diagnosis of *Campylobacter*iosis is based on the recovery of the organism from stool specimens by microaerophilic culture. Current recommendations for the recovery of *Campylobacter* stipulate that cultures be held for a minimum of 72 h prior to signing out a negative result;[3] however, a recent laboratory surveillance by the Centers for Disease Control and Prevention found that, of laboratories surveyed, 66% reported negative results at 48 h, while only 33% reported negative results after 72 h.[4] In contrast to traditional culture methods, more rapid methods for the detection of *Campylobacter* antigens in stool, including enzyme immunoassay (EIA) and lateral flow systems, require only 1 to 2 h until results.[5]

PRINCIPLE

Campylobacter Rapid Test Cassette (Feces) is based on the use of a membrane technology with colloidal gold. A nitrocellulose membrane is sensitized with antibody directed against *Campylobacter*. The test's specificity is ensured by an antibody specific to a *Campylobacter* antigen that is conjugated to the colloidal gold. This conjugate is dried on a membrane.

The fecal sample must be diluted into the extraction buffer that is supplied with the test kit. When extracted specimen come into contact with the strip, the conjugate migrates with the sample by passive diffusion and the conjugate and sample material come into contact with the anti-*Campylobacter* antibody in the T line. If the sample contains the *Campylobacter* antigen, the conjugate-antigen complex will remain bound to the anti-*Campylobacter* reagent and a colored line will develop. Solution continues to migrate to encounter a second reagent that binds the migration control conjugate, thereby producing a colored control line that confirms that the test is working properly. The result is visible within 10 minutes.

REAGENTS

The test contains anti-*Campylobacter* antibody particles and anti-*Campylobacter* antibody coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the 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.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The fecal specimen must be collected in clean, dry, waterproof container containing no detergents, preservatives or transport media.
- Bring the necessary reagents to room temperature before use.

MATERIALS

Materials Provided

- Test Cassettes
- Package Insert
- Specimen Collection Tubes with Extraction Buffer
- Droppers

Materials Required But Not Provided

- Specimen collection containers
- Timer

DIRECTIONS FOR USE

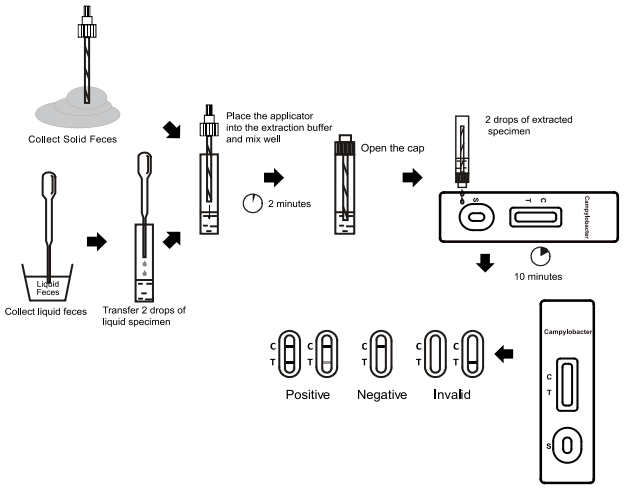
Specimen preparation procedure:

1. To collect fecal specimens:
   Collect sufficient quantity of feces (1-2 mL or 1-2g) in a clean, dry specimen collection container to obtain enough pathogens. 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, then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Leave the collection tube for reaction for 2 minutes.
2. Bring the pouch to room temperature before opening it. Remove the test cassette 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.
3. Hold the specimen collection tube upright and **unscrew the tip** of the specimen collection tube. Invert the specimen collection tube and **transfer 2 full drops of the extracted specimen** (approximately 80 µL) to the specimen well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
4. 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 tube. Collect 80 µL of supernatant, dispense into the specimen well (S). Start the timer and continue from step 4 onwards in the above instructions for use.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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

***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of *Campylobacter* antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: **One colored line appears in the control line region (C)**. No 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.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal valid procedural control. It confirms sufficient specimen volume and correct procedural technique.

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 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 or negative test result does not rule out the possibility that other pathogens may be present.

This test is an acute-phase screening test. Specimens that are collected after this phase may contain antigen titres below the test's sensitivity threshold. If a sample test negative, despite the observed symptoms, further testing with alternative methods are recommended.

PERFORMANCE CHARACTERISTICS

Sensitivity - Specificity

The performance of *Campylobacter* Rapid Test Cassette (Feces) has been evaluated with 139 clinical specimens collected from children in comparison with Latex agglutination. The results show that the relative sensitivity of the *Campylobacter* Rapid Test Cassette (Feces) is 95.2% and relative specificity is 93.5%.

Method		Latex agglutination		Total Results
***Campylobacter* Rapid Test Cassette (Feces)**	Results	Positive	Negative	
	Positive	59	5	64
	Negative	3	72	75
Total Results		62	77	139

Relative sensitivity: 95.2% (95%CI*: 86.5%~99.0%);
Relative specificity: 93.5% (95%CI*:85.5%~97.8%);
Accuracy: 94.2% (95%CI*: 89.0%~97.5%). *Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 3 replicates of four specimens: negative, low titer positive, middle titer positive and high titer positive specimens. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 3 independent assays on the same four specimens: negative, low titer positive, middle titer positive and high titer positive specimens. Three different lots of the *Campylobacter* Test Cassette (Feces) have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-Reactivity

Cross reactivity with following organisms has been studied at 1.0 x 10^7 organisms/mL. The following organisms were found negative when tested with the *Campylobacter* Rapid Test Cassette (Feces).

Citrobacter freundii	Clostridium difficile	Candida albicans
Chlamydia trachomatis	Echovirus	Enterococcus faecium
E.coli	Enterococcus faecalis	Gardnerella vaginalis
Neisseria gonorrhea	Proteus mirabilis	Proteus vulgaris
Pseudomonas aeruginosa	Rotavirus	Adenovirus
Salmonella	Shigella dysenteriae	Shigella flexneri
H.pylori	Corynebacterium diphtheria	

BIBLIOGRAPHY

1. Adedayo O, Kirkpatrick BD. 2008. *Campylobacter* jejuni infections: update on presentation, diagnosis, and management. Hosp. Phys. 44:9–15.

2. Allos BM. 2001. *Campylobacter* jejuni infections: update on emerging issues and trends. Clin. Infect. Dis. 32:1201–1206.Garcia L. et al.; Detection of *Campylobacter* and Cryptosporidium parvum antigens in human fecal specimens using the ColorPac combination rapid solid-phase qualitative immunochromatographic assay; Journal of Cinical Microbiology, p.1267-1268, Mar. 2000.

3. Garcia LS (ed). 2007. Fecal culture for *Campylobacter* and related species, p 3.8.2.5–3.8.2.14. In Clinical microbiology procedures handbook, 3rd ed. LSG & Associates, Santa Monica, CA.McIver C.J. et al.; Diagnosis of enteric pathogens in children with gastroenteritis; Pathology 33(3): 353-8, Aug. 2001.

4. M'ikanatha NM, Dettinger LA, Perry A, Rogers P, Reynolds SM, Nachamkin I. 2012. Culturing stool specimens for *Campylobacter* spp., Pennsylvania, U. S. A. Emerg. Infect. Dis. doi:10.3201/eid1803.111266.MS Wolfe; Giardiasis; Clinical Microbiology Review, Vol5: 93-100, 1992.

5. Granato PA, Chen L, Holiday I, Rawling RA, Novak-Weekley SM, Quinlan T, Musser KA. 2010. Comparison of Premier CAMPY enzyme immunoassay (EIA), ProSpecT *Campylobacter* EIA, and ImmunoCard STAT! CAMPY tests with culture for laboratory diagnosis of *Campylobacter* enteric infections. J. Clin. Microbiol. 48:4022– 4027.

Index of Symbols

	Attention, see instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		Consult Instructions For Use

ACRO BIOTECH, Inc.
4650 Arrow Highway,
Suite D-6 Montclair, CA 91763, U.S.A.
Tel: +1 (909) 541-5085 www.acrobiotech.com

EC REP
MedNet EC-REP GmbH
Borkstrasse 10
48163 Muenster
Germany

Number: 145933402
Revision Date: 2023-07-12