FRENOVO

Campylobacter Rapid Test Kit

Instructions For Use

PRODUCT NAME

Campylobacter Rapid Test Kit

PACKAGE SPECIFICATION

25 tests/kit

INTENDED USE

The kit is a rapid chromatographic immunoassay for the qualitative detection of Campylobacter antigen in human feces specimen. It is used as an assistant tool for the diagnosis of Campylobacter infection.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Campylobacteriosis is an infectious disease caused by bacteria of the genus Campylobacter. Most people who become ill with campylobacteriosis get diarrhoea, cramping, abdominal pain, and fever within two to five days after exposure to the organism. The diarrhoea may be bloody and can be accompanied by nausea and vomiting. The illness typically lasts one week. Some infected persons do not have any symptoms. In persons with compromised immune systems, Campylobacter occasionally spreads to the bloodstream and causes a serious life-threatening infection.

Campylobacter Rapid Test Kit is a qualitative lateral flow immunoassay for the detection of Campylobacter in human feces samples. The membrane is pre-coated with antibodies against Campylobacter antigens on the test line region. During testing, the sample reacts with the particle coated with anti-Campylobacter antibodies which was pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane will react with the mixture conjugates and generate coloured lines. A red band will appear in the quality control area (c) regardless of whether Campylobacter antigen is present in the sample or not. The red band in the quality control area (c) is the standard to determine whether there are enough samples and whether the chromatographic process is normal, and it is also the internal control standard of reagents.

KIT COMPONENTS

Each kit contains:

1. Test devices: 25 pieces test devices individually pouched.
2. Sample collection tubes: 25 pieces tubes and 1.0 ml collection solution in each tube.
3. Instructions For Use: 1 copy attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Biohazard disposal waste container.
- Disposable gloves and/or protective clothing.

WARNINGS

1. Read the Instructions For Use completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. FRENOVO Campylobacter Rapid Test Kit is for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. The kit is for professional use only.
2. The Instructions For Use must be followed to ensure optimum test performance.
3. The kit is intended for in vitro diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.

Safety Precautions

1. Standard precautions for handling infectious agents should be observed when using this kit.
2. Wear protective clothing such as lab coat, safety glasses and disposable gloves when handling specimens and assay reagents.
3. Wash hands thoroughly after use.
4. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Bio safety Precautions

Appropriate bio safety practices should be used when handling specimens and reagents. These precautions include, but are not limited to the following:

1. Do not smoke,eat,drink,apply cosmetics or handle contact lenses in areas in which specimens are handled.
2. Dispose of all specimens, used devices and tubes as though they are capable of transmitting infection. The preferred methods of disposal are by autoclave at 121°C for a minimum of 60 minutes or by incineration. Disposable materials may be incinerated. Liquid waste may be mixed with appropriate chemical disinfectants. A solution of 10% bleach is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions containing bleach.
3. When disposing of sample collection tubes, avoid contact with acid to prevent liberation of a toxic gas.
4. All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
5. Use a separate tube and device for each specimen tested.

Handling Precautions

1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix sample collection tubes/test devices from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. The result should be read immediately after the end of the 10 minutes incubation time following the addition of collected specimen. Do not read results beyond 15 minutes.

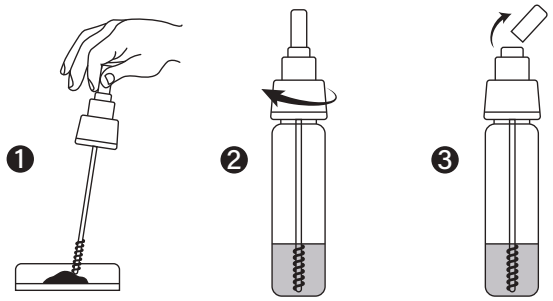
STORAGE INSTRUCTIONS

1. The kit should be stored between 2-30°C and the shelf life is 24 months.
2. The kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the extraction Solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
4. Do not freeze the kit.

TEST PROCEDURE

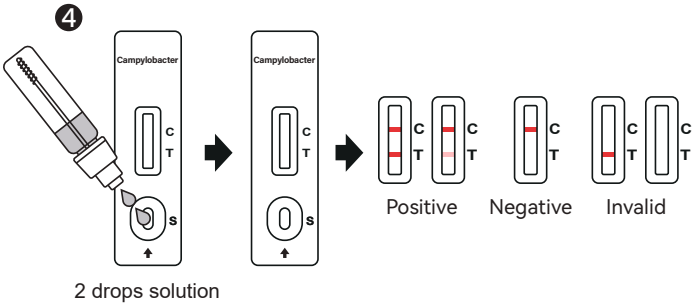
Allow the test device, specimen, extraction solution to equilibrate to room temperature (15-30°C) prior to testing.

1. Loosen the sample collection tube, take out the sampling rod, insert the feces sample, pick up 50 mg fecal sample (equivalent to the size of match head) and then put the sampling rod back into the tube, and rotate it tighten and shake well.
2. Place the test cassette on a clean and level surface. Break the tip of the sample collection tube, abandon the first two drops and draw two drops (approximately 90ul) into the sample well then start the timer. Avoid trapping air bubbles in the sample well.
3. Wait for the colored line(s)to appear. The test result should be read at 10 minutes. Do not interpret the result after 15 minutes.



Sampling rod

Screw the cap back to the buffer bottle



INTERPRETATION OF RESULTS

Negative result: if there is only a quality control line C, the detection line is colorless, indicating that Campylobacter antigen has not been detected and the result is negative.

Positive result: if both the quality control line C and the detection line appear, the Campylobacter antigen has been detected and the result is positive.

Invalid result: if the quality control line C is not observed, it will be invalid regardless of whether there is detection line (as shown in the figure above), and the test shall be conducted again.

LIMITATIONS

1. Campylobacter Rapid Test Kit will only indicate the presence of Campylobacter in the specimen (qualitative detection) and should be used for the detection of Campylobacter antigens in feces specimens only. Neither the quantitative value nor the rate of increase in antigen concentration can be determined by this test.
2. Campylobacter Rapid Test Kit has been validated only with human stool samples. Some stool samples can decrease the intensity of the control line.
3. Freezing and thawing cycles for the sample are not recommended, it could cause wrong results.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Campylobacter infection.
5. This test provides a presumptive diagnosis of Campylobacteriosis. All results must be interpreted together with other clinical information and laboratory findings available to the physician.
6. Mucous and/or bloody stool samples could cause non-specific reactions in the test. Mucous and/or bloody stool samples whose result is positive should be followed up with other techniques to confirm the result.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

It was performed an evaluation using Campylobacter Rapid Test Kit vs a commercial qPCR kit (Campylobacter Real Time PCR Detection Kit). The specimens were obtained from patients with the same as Campylobacter infection symptoms.

clinical study		qPCR		
Campylobacter Rapid Test Kit	Results	Positive	Negative	Total Results
	Positive	62	1	63
	Negative	2	58	60
Total Results		64	59	123

Accuracy Results:

Clinical sensitivity=96.88% (89.16% ～ 99.62%)
Clinical specificity =98.31% (90.91% ～ 99.96%)
Accuracy =97.56% (93.04% ～ 99.49%)

Cross Reaction

TCross reactivity with following organisms has been studied at 1.0 x 107 organisms/ml. The following organisms were found negative when tested with the Campylobacter Rapid Test Kit.

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	

INDEX OF SYBOML

IVD	In vitro diagnostic medical device		single-use, Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
2℃ 30℃	Temperature limit	LOT	Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
	Biological risks		

Hangzhou Frenovo Biotech Co., Ltd.
Address: Room 401,Building 26, Room 401&301,Building 27,No.488-1,Donghu North Road, Donghu Street,LinPing District,Hangzhou City,Zhejiang Province.China.
Tel: +86-571-89170657
Email: business@frenovo.com

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