FRENOVO

Clostridium difficile antigen GDH Rapid Test Kit

Instructions For Use

PRODUCT NAME

Clostridium difficile antigen GDH Rapid Test Kit

PACKAGE SPECIFICATION

25 tests/kit

INTENDED USE

Clostridium difficile antigen GDH Rapid Test is an in vitro qualitative immunochromatographic assay for the rapid detection of Clostridium difficile Glutamate Dehydrogenase (GDH) antigen in stool samples. The test offers a simple and highly sensitive screening assay to make a presumptive diagnosis of Clostridium difficile infection.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Clostridium difficile (C. difficile), a Gram-positive spore bearing anaerobic bacterium is the major aetiological agent of diarrhoea and colitis associated with antibiotics. C. difficile is the most common cause of health care-associated diarrhoea in developed countries and is a major source of nosocomial morbidity and mortality worldwide. Disease due to C. difficile develops when the organism is allowed to proliferate in the colon, most commonly after antibiotic use has eliminated competing flora. 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.

Clostridium difficile antigen GDH Rapid Test is a sandwich solid phase immunochromatographic assay. To perform the test, an aliquot of diluted stool sample is added to the sample well of the test cassette. The sample flows through a pad containing antibodies against GDH coupled to red-colored colloidal gold. If the sample contains GDH antigen, the antigen will bind to the antibody coated on the colloidal gold particles to form antigen-antibody-gold complexes. These complexes move on the nitrocellulose membrane by capillary action toward the test line region on which GDH specific antibodies are immobilized separately. As the complexes reach the test line, they will bind to the antibody corresponding to the Clostridium difficile antigen on the membrane to form of a line. A red control line will always appear in the result window to indicate that the test has been correctly performed and the test device functions properly. If GDH antigen is not present or lower than the detection limit of the test, only the control line will be visible. If the control line dose not developed, the test is invalid.

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 piece 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. The 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 instructions 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.

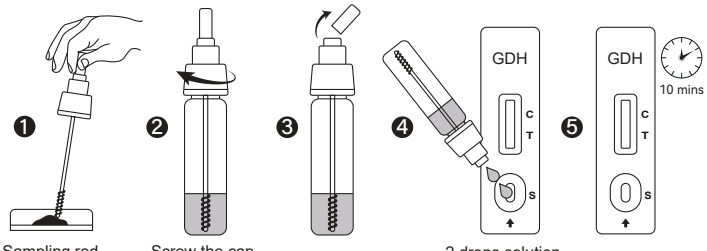
STORAGE INSTRUCTIONS

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.

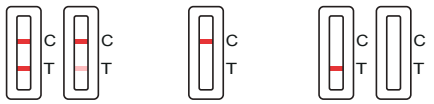


INTERPRETATION OF RESULTS

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

Positive result: Two lines appear on test strip. One colored line should be in the control line region(C), and one colored lines should appear in test line region(T). The color intensities of the lines do not have to match, indicating that GDH antigen has been detected.

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.



Positive Negative Invalid

LIMITATIONS

1. The kit is for professional in vitro diagnostic use only. The test should be used for the detection of GDH antigen in human feces samples. Neither the quantitative value nor the rate of increase in GDH antigen can be determined by this qualitative test.
2. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
3. A negative result may be obtained if the concentration of the GDH antigen present in the specimen is not adequate or is below the detectable level of the test.
4. The accuracy of the test depends on the quality of the sample, false negatives may result from improper sample collection or storage.
5. Bloody stool samples can contain components that may cause non-specific reactions in the test. Every bloody stool sample whose result is positive should be followed up with other techniques of diagnosis to confirm the result.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity
Clinical study was performed to compare the results obtained by The kit and qPCR. The results indicated that The kit has a high sensitivity and specificity as summarized below:

GDH clinical study		qPCR		Total Results
Clostridium difficile antigen GDH Rapid Test Kit	Results	Positive	Negative	
	Positive	53	1	54
	Negative	2	75	77
Total Results		55	76	131

Clinical sensitivity=96.36% (95%CI * 92.3– 99.3%)
Clinical specificity=98.68% (95%CI * 96.0–99.7%)
Accuracy=97.71% (95%CI * 92.61% to 99.66%)

Cross Reaction
An evaluation was performed to determine the cross reactivity of Clostridium difficile antigen GDH Rapid Test ; no cross reactivity against gastrointestinal pathogens, other organism, substances and/or faecal markers occasionally present in faeces:

Adenovirus Astrovirus Bovine Haemoglobin Bovine Lactoferrin Bovine Transferrin Campylobacter coli Campylobacter jejuni Streptococcus pyogenes Salmonella paratyphi A Human Lactoferrin Clostridium perfringens	Entamoeba histolytica Escherichia coli O111 Escherichia coli O26 Escherichia coli O157 Giardia Helicobacter pylori Human Calprotectin Clostridium difficile Toxin A Yersinia Enterocolitica O:3 Salmonella typhi Human Transferrin
Legionella pneumophila Listeria monocytogenes Norovirus GI Norovirus GII Pig Haemoglobin Salmonella enteritidis Human Haemoglobin Clostridium difficile Toxin B Yersinia Enterocolitica O:9	Salmonella typhimurium Shigella boydii Shigella dysenteriae Shigella flexneri Shigella sonnei Streptococcus pneumococcal

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		

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