FRENOVO

Norovirus Rapid Test Kit

Instructions For Use

PRODUCT NAME

FRENOVO Norovirus Rapid Test Kit

PACKAGE SPECIFICATION

25 tests/kit

INTENDED USE

FRENOVO Norovirus Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of Norovirus in human faeces specimens to aid in the diagnosis of Norovirus infection.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Noroviruses (NoV) are a genetically diverse group of single stranded RNA, nonenveloped viruses belonging to the Caliciviridae family. For decades they were called “small round structured viruses” (SRSV) or “Norwalk-like viruses” until recently when their taxonomy was investigated using modern molecular techniques. Initially four antigenic types of SRSV were recognized, but more recently three genogroups have been identified with the genus Norovirus. Genogroup 1 and Genogroup 2 are associated with human infections whilst Genogroup 3 is associated with bovine and porcine infection. Noroviruses are a major cause of acute gastroenteritis worldwide, often causing explosive outbreaks in institutions. They are highly contagious, with an inoculum of as few as ten particles being able to cause infection. Transmission occurs through ingesting contaminated food and water and by person-to-person spread. Transmission is predominantly faecal-oral but may be airborne due to aerosolization of vomitus, which typically contains abundant infectious virus particles. Outbreaks may involve several routes of transmission. The illness is acute, usually mild, although it has caused fatalities among the frail elderly, and self-limiting and follows an incubation period of 24-48 hours although cases can occur within 12 hours of exposure. The ability of Noroviruses to cause outbreaks in institutions has become a major public health issue. Outbreaks of Norovirus infection can be associated with restaurants and institutions as diverse as nursing homes, hospitals and elite sporting camps. Infections in infants, elderly or frail patients can be fatal if left untreated.

The symptoms of Norovirus illness usually include nausea, vomiting, diarrhoea, and some stomach cramping. Sometimes people additionally have a low-grade fever, chills, headache, muscle aches, and a general sense of tiredness. The illness often begins suddenly, and the infected person may feel very sick. In most people the illness is self-limiting with symptoms lasting for about 1 or 2 days. In general, children experience more vomiting than adults.

FRENOVO Norovirus Rapid Test Kit is a qualitative, lateral flow immunoassay for the detection of Norovirus in human faeces specimens. The assay uses Genogroup 1 and Genogroup 2 specific monoclonal antibodies coated on the test membrane. During testing, the stool specimen reacts with the conjugate antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with Genogroup 1 and 2 antibodies on the membrane and generates a coloured line at the level of the T zone respectively. The presence of a coloured line in T region indicates a positive result for Genogroup 1 or Genogroup 2 respectively, while its absence indicates a negative result. To serve as a procedural control, a coloured line will always appear in the control reaction zone (C) indicating that proper volume of specimen has been added and membrane wicking has occurred.

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

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.

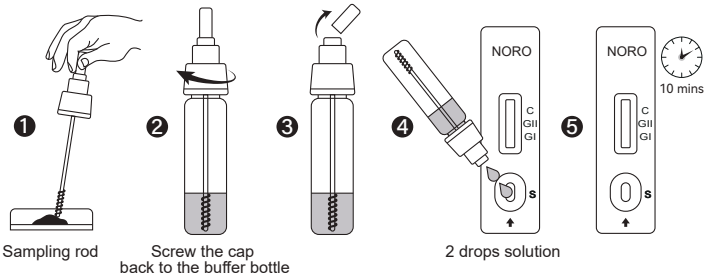
STORAGE INSTRUCTIONS

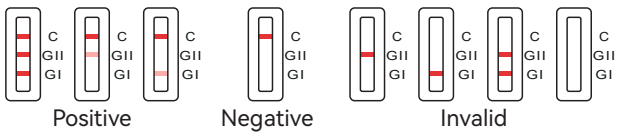
1. The kit should be stored between 2-30°C and the shelf life is 24 months.
2. The kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date 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 cassette, specimen, buffer 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

Genogroup 1 POSITIVE:* Two distinct colored lines appear. One colored line should be in the control line region (C) and another apparent colored line should be

in the GI region.

Genogroup 2 POSITIVE:* Two distinct colored lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the GII region.

Genogroup 1& Genogroup 2 POSITIVE:* Three distinct colored lines appear. One colored line should be in the control region (C) and two colored line should be in the GI region and GII region. A positive result in the GI region and GII region indicates that Genogroup 1 antigen and Genogroup 2 antigen were detected in the sample.

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

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line regions ((GI/GII)).

INVALID: Control line (C) 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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The kit is for professional in vitro diagnostic use only. The test should be used for the detection of Norovirus in feces samples. Neither the quantitative value nor the rate of increase in Norovirus 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 Norovirus 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. Stool sample from infant under one year old can produce a false positive result.
5. The use of over-the-counter and prescription medicine at high concentrations can interfere with results, leading to either invalid or incorrect test results.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

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

Clinical samples		PCR		
Norovirus Rapid Test Kit	Results	Positive	Negative	Total Results
	Positive	44	1	45
	Negative	2	99	101
Total Results		46	100	146

Clinical sensitivity=95.65% (95%CI * 85.16% to 99.47%)
Clinical specificity=99.00% (95%CI * 94.54% to 99.97%)
Accuracy=97.95% (95%CI * 94.11% to 99.57%)

Cross Reaction

Cross reactivity with following organisms has been studied at 1.0x107 org/ml. The following organisms were found negative when tested with FRENOVO Norovirus Rapid Test Kit.

Corynebacterium diphtheria	Proteus vulgaris
Neisseria gonorrhea	Gardnerella vaginalis
Shigella sonnei	Shigella dysenteriae
Pseudomonas aeruginosa	Enterococcus faecium
Shigella flexneri	Helicobacter pylori
Clostridium difficile	Candida albicans
Enterococcus faecalis	Proteus mirabilis
E.coli	/

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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