FRENOVO

Rota Rapid Test Kit

Instructions For Use

PRODUCT NAME

FRENOVO Rota Rapid Test Kit

PACKAGE SPECIFICATION

25 tests/kit

INTENDED USE

FRENOVO Rota Rapid Test Kit is an in vitro qualitative immunochromatographic assay for the rapid detection of rota virus antigens in human stool specimen. The test results are intended to aid in the diagnosis of rota virus infection and to monitor the effectiveness of therapeutic treatment.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Rota virus is the primary causative agent of pediatric gastroenteritis and diarrhea worldwide. The improvement of food, water, and hygiene has done nothing to decrease the incidence of rota virus disease. Almost every child on the planet may get infected by age 5. Scientists say that families of the 900,000 young children around the world who die each year from rota viruses. Many of them get it between December and April in the temperate climates of the northern hemisphere. Most of these deaths occur in developing countries. The infection usually begins with a fever. Soon the little one begins to vomit and has a nasty tummy-ache. The vomiting goes away, followed by watery diarrhea that lasts from 3 to 9 days. Most of the time, kids recover with little difficulty. Sometimes, severe dehydration results. The extreme dehydration that can be caused by rota viruses is second only to the dehydration caused by cholera. The infection starts suddenly and lasts for an average of four to six days. Rota viruses are extremely contagious. Only a very few particles are needed to transmit infection. They originate in the stool, but are found throughout the environment wherever young children spend much time, especially during the winter months. They are resistant to disinfectants used to clean surfaces and to anti-bacterial hand-washing agents. Rota virus particles remain active on human hands for at least 4 hours, on hard dry surfaces for 10 days, and on wet areas for weeks. Untreated, rota virus infection may result in severe illness with dehydration and disturbances of the body' s normal electrolyte balance, especially in babies and preschool children. Rota virus is the cause of up to 50% of the hospitalized cases of diarrheal illness in infants and young children. Rota virus induced dehydration is a major cause of infant morbidity in both developed and underdeveloped countries, and a major cause of infant mortality in the developing countries. The highest prevalence of the disease is experienced in temperate climates during the cooler months of the year. In tropical climates, rota virus infection can occur all year round. The age groups most susceptible to the disease are that of infants and children.

FRENOVO Rota Rapid Test Kit 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 rota virus coupled to red-colored colloidal gold. If the sample contains rota virus antigens, 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 rota virus specific antibodies are immobilized separately. As the complexes reach the test line, they will bind to the antibody corresponding to the rota virus 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 virus 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 1.0ml 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.

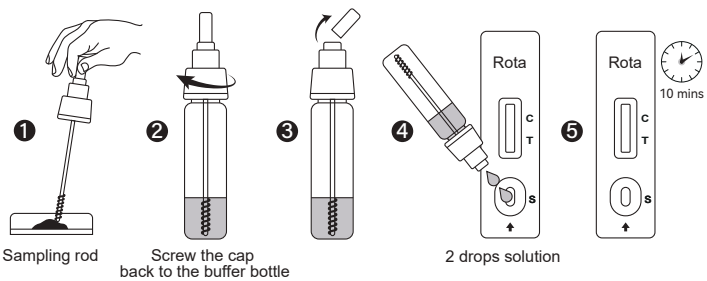
STORAGE INSTRUCTIONS

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.

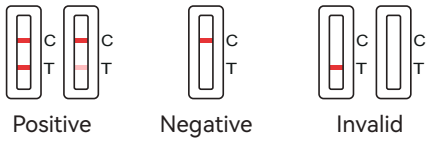


INTERPRETATION OF RESULTS

Negative result: if there is only a quality control line C, the detection line is colorless, indicating that Rota virus 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. The color intensities of the lines do not have to match. the result is positive for rota virus infection.

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 Rota in human feces samples. Neither the quantitative value nor the rate of increase in Rota 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 Rota 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. 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:

Rota clinical study		PCR		Total Results
Rota Rapid Test Kit	Results	Positive	Negative	
	Positive	57	0	57
	Negative	3	122	125
Total Results		60	122	182

Clinical sensitivity=95.00% (95%CI * 86.08% to 98.96%)
Clinical specificity>99.00% (95%CI * 97.57% to 100.0%)
Accuracy=98.35% (95%CI * 95.26% to 99.66%)

Cross Reaction
Cross reactivity with following organisms has been studied at 1.0 x 107 org/ml. The following organisms were found negative when tested with FRENOVO Rota 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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