CE IVD

FRENOVO

Salmonella Typhi Antigen Rapid Test Kit

Instructions For Use

PRODUCT NAME

FRENOVO Salmonella Typhi Antigen Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

FRENOVO Salmonella Typhi Antigen Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of Salmonella typhi antigens in human feces specimens to aid in the diagnosis of Salmonella typhi infection.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Typhoid fever is a life threatening illness caused by the bacterium Salmonella typhi, and was observed by Eberth (1880) in the mesenteric nodes and spleen of fatal cases of typhoid fever. The infection is acquired typically by ingestion. On reaching the gut,the bacilli attach themselves to the epithelial cells of the intestinal villi and penetrate to the lamina and submucosa. They are then phagocytosed there by polymorphs and macrophages.The ability to resist intracellular killing and to multiply within these cells is a measure of their virulence. They enter the mesenteric lymph nodes, where they multiply and, via the thoracic duct, enter the blood stream.

FRENOVO Salmonella Typhi Antigen Rapid Test Kit is a qualitative, lateral flow immunoassay for the detection of S. typhi antigens in human feces. In this test, the membrane is pre-coated with anti-S.typhi antibodies on the test line region of the test. During testing,the specimen reacts with the particle coated with anti-S.typhi antibodies.The mixture migrates upward on the membrane by capillary action to react with anti-S.typhi antibodies on the membrane and generate a colored line.The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result.To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

KIT COMPONENTS

Each kit contains:

1. Test devices: 20 pieces test devices individually pouched.
2. Sample collection tubes: 20 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.

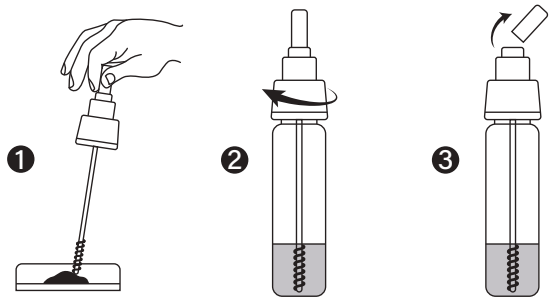
STORAGE INSTRUCTIONS

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

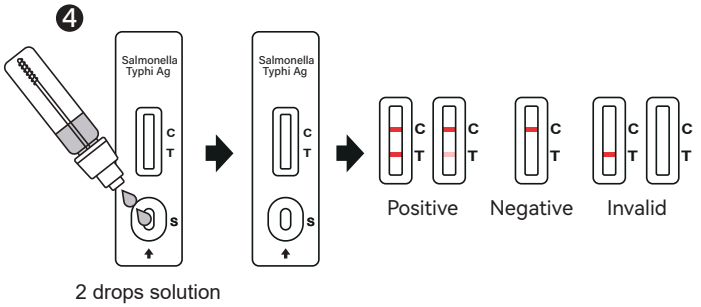
Allow the test device, specimen, extraction solution to equilibrate to room temperature (15-30°C) prior to testing.

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.



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 Salmonella Typhi has not been detected and the result is negative.

Positive result: if both the quality control line C and the detection line appear, the Salmonella Typhi 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. The kit is for professional in vitro diagnostic use only. The test should be used for the detection of Salmonella Typhi in feces samples. Neither the quantitative value nor the rate of increase in Salmonella Typhi 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 Salmonella Typhi 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		Total Results
Salmonella Typhi Antigen Rapid Test Kit	Results	Positive	Negative	
	Positive	50	1	51
	Negative	2	101	103
Total Results		52	102	154

Clinical sensitivity=96.15% (95%CI * 86.79% to 99.53%)
Clinical specificity=99.02% (95%CI * 94.66% to 99.98%)
Accuracy=98.05% (95%CI * 94.41% to 99.60%)

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 Salmonella Typhi Antigen 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°C 30°C	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	CE	CE mark

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INSTRUCTION APPROVAL AND REVISION DATE

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