H.Pylori(HP) Antigen Rapid Test Kit

PRODUCT NAME

H.Pylori(HP) Antigen Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

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

SUMMARY AND PRINCIPLES OF THE PROCEDURE

H. Pylori is associated with a variety of gastrointestinal diseases including gastritis, duodenal and gastric ulcer, non-ulcer dyspepsia, gastric adenocarcinoma and lymphoma. H.Pylori plays the exact role in gastrointestinal disease still needs to be precisely defined and is the subject of ongoing research. However, the prevalence rates for H.Pylori infection as demonstrated by histological and bacteriological methods can approach 90% in patients who present clinical symptoms of the gastrointestinal diseases listed above. After the oral infection of H.pylori reached the gastric mucosa, it was caused by chronic and superficial gastritis for weeks or months. It developed into duodenal ulcer, gastric ulcer, lymphoproliferative gastric lymphoma, chronic atrophic gastritis and so on The common symptoms of chronic gastritis and peptic ulcer patients are: after eating, the upper abdomen is full, uncomfortable or painful, and often accompanied by other adverse symptoms, such as belching, abdominal distention, acid and appetite loss. Some patients can also have recurrent severe abdominal pain, small amount of bleeding in upper digestive tract, etc.

The double antibody sandwich method is used in the test kit. The kit contains the antibody of Helicobacter Pylori fixed in the detection area (T) of the membrane in advance. During the detection, the collected feces sample is dropped into the sample (s) well, and then the chromatography is carried out upward under the capillary effect. If it is positive, the sample contains Helicobacter Pylori, and a red band appears in the test area (T). If it is negative and there is no Helicobacter Pylori in the sample, there will be no red band in the test area (T). A red band will appear in the quality control area (c) regardless of whether Helicobacter Pylori 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: 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 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 H. Pylori(HP) Antigen Rapid Test 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 20 minutes.

STORAGE INSTRUCTIONS

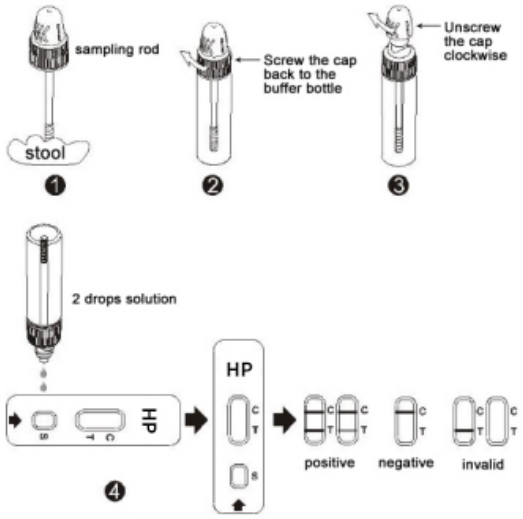
1. The kit should be stored between 2-30°C and the shelf life is 24 months.
2. The kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date 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 20 minutes.



INTERPRETATION OF RESULTS

Negative result: if there is only a quality control line C, the detection line is colorless, indicating that HP 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 HP 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. The kit is for professional in vitro diagnostic use only. The test should be used for the detection of HP antigen in feces samples. Neither the quantitative value nor the rate of increase in HP antigen can be determined by this qualitative test.
2. The kit will only indicate the presence of human blood in the specimen or not.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. A negative result may be obtained if the concentration of the HP antigen present in the specimen is not adequate or is below the detectable level of the test.
5. The accuracy of the test depends on the quality of the sample, avoid hematuria, haemorrhoids or menstruation contaminate feces samples. False negatives may result from improper sample collection or storage.
6. 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

143 clinical samples were tested by the kit,73 were negative by gastroscopy and 70 were positive by gastroscopy. The results showed that the test kit had high sensitivity to H.pylori antigen, and its relative sensitivity was higher than 99%, specificity was higher than 99%, accuracy was higher than 99%.

HP clinical study		Gastroscopy		
H. Pylori(HP) antigen rapid test kit	Results	Positive	Negative	Total Results
	Positive	70	0	70
	Negative	0	73	73
Total Results		70	73	143

Accuracy Results:

Clinical sensitivity >99.0 % (95%CI* 94.9%~100.0%)

Clinical specificity >99.0 % (95%CI*95.1%~100.0%%)

Accuracy >99.0 % (95%CI*97.5%~100.0%)

Interference Substances

The following potential interfering substances have been tested using FRENOVO H. Pylori(HP) antigen rapid test(Whole Blood/ Serum/ Plasma)and no interference was observed:

Substance	Tested Concentration
Ascorbic	20 mg/dL
Hemoglobin	1000 mg/dL
Bilirubin	60 mg/dL
Triglyceride	500 mg/dL

Cross Reaction

The following organisms were tested at $1.0x10^7$ org/ml and has no effect on the negative and positive test results of this reagent, and there is no cross-reaction.

Staphylococcus aureus	Neisseria gonorrhea
Pseudomonas aeruginosa	Group B Streptococcus
Enterococcus faecalis	Proteus vulagris
Group C Streptococcus	Enterococcus faecium
Klebsiella pneumoniae	Proteus mirabilis
Branhamella catarrhalis	Acinetobacter spp
Hemophilus influenzae	Salmonella choleraesius
Candida albicans	Gardnerella vaginalis
Neisseria meningitides	Acinetobacter calcoaceticus
Chlamydia trachomatis	E.coli
Rotavirus	Adenovius

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	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
CE	CE mark		Biological risks

Hangzhou Frenovo Biotech Co., Ltd.
Address: Room 401,Building 36,No.488-1,Donghu North Road, Donghu Street, Yuhang District, Hangzhou City, Zhejiang Province, China.
Tel: 86-0571-89170657
Email: business@Frenovo.com

EC REP
Lotus NL B.V.
Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Email: peter@lotusnl.com

INSTRUCTION APPROVAL AND REVISION DATE

Revision Date:
Date of Issue: