H. Pylori(HP) Antibody Rapid Test Kit

PRODUCT NAME

H. Pylori(HP) Antibody Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

The kit is a lateral flow, qualitative immunoassay. It is intended for use at point of care facilities to detect the presence of IgG antibodies specific to Helicobacter Pylori (H. Pylori) in human blood, serum or plasma. It provides an aid in the diagnosis of infection by H. Pylori.

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. No evidence shows that H. Pylori can invade the blood stream since no isolates yet have been detected using commercial blood culture methods. Human populations are infected by H. Pylori throughout the world. In developed countries, about 50% of the population may have H. Pylori infection by the age of 60 years, while only 10-20% of adults in the third decade of life have it.

The kit detects IgG antibodies specific to H.Pylori infection in patient's blood, serum or plasma. It is a non-invasive method and does not use radioactive isotopes; the assay procedures are easy and do not require professional training; it provides a rapid result. It is a useful on-site aid in the diagnosis of H.Pylori infection.

This assay is a double antigen chromatographic lateral flow immunoassay. The test strip in the device includes: 1) a burgundy-colored conjugate pad containing colloidal gold coupled with H.Pylori antigens, and 2) nitrocellulose membrane containing a test line (T line) and a control line (C line). The T line is coated with H.Pylori recombinant antigens. When IgG antibodies specific to H.Pylori are present in the specimen, the T line will become a burgundy-colored band. If antibodies to H.Pylori are not present or are present below the detectable level, no T line will develop. The C line should always appear as a burgundy-colored band regardless of the presence of antibodies to H.Pylori. The C line serves as an internal qualitative control of the test system to indicate that an adequate volume of specimen has been applied and the flow occurred.

MATERIALS PROVIDED

Each kit contains:

1. Test Devices: 20 pieces test devices individually pouched.
2. Wash Buffer Solution: 1.5 ml in dropper bottle.
3. Droppers: 20 pieces droppers of 25 ul
4. Instructions For Use: 1 copy attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Specimen collection containers
- Disposable gloves and/or protective clothing
- Centrifuge(for plasma only)
- Micropipette
- Lancets(for fingertip whole blood only)

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 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 wash buffer, 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 dropper 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 wash buffer solution/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 specimen and wash buffer solution. 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 wash buffer 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.

SAMPLE COLLECTION AND PREPARATION

1. Applicable samples： Whole Blood/Serum/Plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear nonhemolysis specimens.
3. Testing should be performed immediately after the specimens have been collected. Do not

leave the specimens at room temperature for prolonged periods.

4. Serum and plasma specimens may be stored at 2~8 ℃ for up to 7 days, for long term storage, serum/plasma specimens should be kept below -20℃. Whole blood collected by venipuncture should be stored at 2~8℃ if the test is to be run within 2 days of collection.
5. Do not freeze whole blood specimens.
6. Whole blood collected by finger stick should be tested immediately.
7. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
8. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.
9. EDTA K2,Heparin sodium,Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

QUALITY CONTROL

An internal procedural control is included in the test. a colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

TEST PROCEDURE

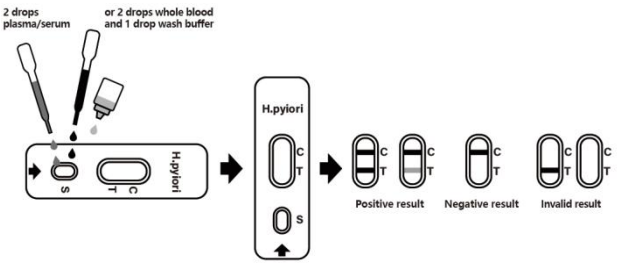
Allow the test device, specimen, extraction solution to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed pouch and use it within one hour. Place the test cassette on a clean and level surface.
2. For Serum or Plasma Specimens

   Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (two drops/approximately 50ul),Avoid trapping air bubbles in the sample well and start the timer.

   For Whole Blood Specimens

   To use a dropper: Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (two drops/approximately 50ul), then add one drop of buffer(approximately 30ul)to the sample well and 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 HP antibodies 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 antibodies has been detected and the result is positive for antigen.

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 in vitro diagnostic use only.The test should be used for the detection of HP antibodies in serum, plasma or whole blood specimens only. Neither the quantitative value nor the rate of increase in HP antibodies concentration can be determined by this qualitative test.
2. The kit will only indicate the presence of HP antibodies in the specimen and should not be used as the sole criteria for the diagnosis of HP infection.
3. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. If the test result is negative and clinical symptoms persist additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of HP infection.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The serum and plasma samples of patients with or without symptoms were detected with The kit) , and the biological methods (culture and / or histology) were used as reference. If the specimen is positive by culture or histology or by both methods, it is regarded as positive; if it is negative by both methods, it is regarded as negative. The results indicated that The kit)has a high sensitivity and specificity as summarized below:

HP clinical study		Biological methods		
H. Pylori(HP) antibody rapid test kit	Results	Positive	Negative	Total Results
	Positive	94	7	101
	Negative	4	85	89
Total Results		98	92	190

Accuracy Results:

Clinical sensitivity =95.92 % (95%CI* 89.88% to 98.88%)

Clinical specificity = 92.39 % (95%CI*84.95% to 96.89%)

Accuracy= 94.21% (95%CI*89.88% to 97.07%)

Interference Substances

The following potential interfering substances have been tested using The kit)and no interference was observed :

Substance	Tested Concentration
Ascorbic	20 mg/dL
Hemoglobin	1000 mg/dL
Bilirubin	60 mg/dL
Oxalic acid	1000 mg/dL
Human serum albumin	2000 mg/dL
Triglyceride	500 mg/dL

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
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: