RapidFor™ H. pylori Ag Rapid Test Kit
Reference Number: VMD16
For Professional use

IVD IFU CE

FOR IN VITRO DIAGNOSTIC USE

This instructions for use (IFU) must be read carefully prior to use. Instructions for use must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions for use.

INTENDED USE

The RapidFor™ H. Pylori Ag Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of H. Pylori antigen in human feces specimens to aid in the diagnosis of H. Pylori infection.

SUMMARY

RapidFor™ H. Pylori is associated with a variety of gastrointestinal diseases included non-ulcer dyspepsia, duodenal and gastric ulcer, and active, chronic gastritis. The prevalence of H. Pylori infection could exceed 90% in patients with signs and symptoms of gastrointestinal diseases. Recent studies indicate an association of H. Pylori infection with stomach cancer. H. Pylori colonizing in the gastrointestinal system elicits specific antibody responses which aids in the diagnosis of H. Pylori infection and in monitoring the prognosis of the treatment of H. Pylori related diseases. Antibiotics in combination with bismuth compounds have been shown to be effective in treating active H. Pylori infection. Successful eradication of H. Pylori is associated with clinical improvement in patients with gastrointestinal diseases providing further evidence.

PRINCIPLE OF THE PROCEDURE

The H. Pylori Ag Rapid Test is a qualitative membrane strip-based immunoassay for the detection of pylori antigen in human feces. In this test procedure, H. Pylori antibody is immobilized in the test line region of the device. After an adequate volume of test specimen is placed in the specimen well, it reacts with H. Pylori antibody coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized H. Pylori antibody. If the specimen contains H. Pylori antigen, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain H. Pylori antigen, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

Composition

The test contains a membrane strip coated with H. Pylori antibody on the test line, goat anti mouse antibody on the control line, and a dye pad which contains colloidal gold coupled with H. Pylori. The quantity of tests was printed on the labeling.

REAGENTS AND MATERIALS SUPPLIED

COMPONENT	20 Test/box
Test Device	20 Test cassettes (1 Test/pouch x 20 pouches)
Buffer	20 single-use bottles filled with 1.5 mL extraction buffer
Sample collection apparatus	20 single-use sample collection apparatus
Packing Insert	1 instruction for use

Materials Required but Not Provided

- Timer or stopwatch
- Specimen collection container

STORAGE AND STABILITY

1.Store as packaged in the sealed pouch at temperature 2~30°C and relative humidity between 40%-60%. The kit is stable within the expiration date printed on the labeling.
2. Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
3. The LOT and the expiration date were printed on the labeling.

WARNINGS AND PRECAUTIONS

1.For professional in vitro diagnostic use only. Do not use after expiration date.
2.Do not eat, drink, or smoke in the area where the specimens and kits are handled.
3.Handle all specimens as if they contain infectious agents.
4.Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
5.Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are assayed.
6.Follow standard biosafety guidelines for handling and disposal of potential infective material.
7.Humidity and temperature can adversely affect results.

SAMPLE COLLECTION AND STORAGE

-The test kit can be performed used on human feces.
-Collect enough feces (1~2ml or 1~2g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assays performed within 6 hours after collection.
-Specimen collected may be stored for 3 days at 2~8°C if not tested within 6 hours. For long term storage, specimens should be kept below -20°C.
-Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the fecal specimen in at least 5 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.
-Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the dilution buffer. Leave the tube alone for 2 minutes.
-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.

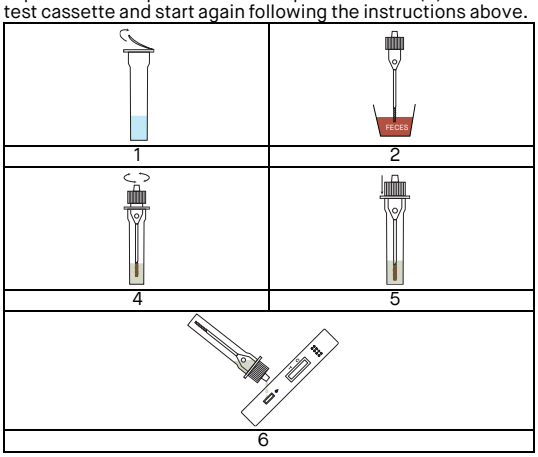
TEST PROCEDURE

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) before testing.
To collect stool specimens:
Collect an adequate amount of feces (1~2 mL) in a clean, dry specimen collection container to obtain maximum antigen (if present).
or 1~2 g) collect. Best results will be obtained if the assay is performed within 6 hours after collection. If collected samples are not tested within 6 hours, they can be stored at 2~8°C for 3 day. For long-term storage, samples should be kept below -20°C.
1. Uncap the tube containing buffer solution and place on a flat surface.
2. Take the specimen collection apparatus and collect approximately 50 mg of stool (equivalent to 1/4 of a pea) by randomly stabbing the stool specimen in at least 3 different places. Do not scoop the stool sample.

3. Place the sample collection apparatus into the tube containing the buffer solution.
4. Swirl the apparatus 15 times in the solution to dissolve the sample in the buffer solution.
5. After the sample and buffer solution are completely mixed, press the apparatus down to seal the tube.

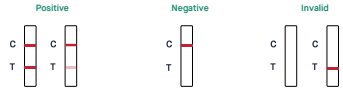
Test Procedure

NOTE: Bring the package to room temperature before opening.
NOTE: Do not open the package until you are ready to test and it is recommended that the disposable test be used within 15 minutes under low ambient humidity (RH≤70%).
NOTE: Best results are obtained if the test is performed immediately after opening the foil pack.
6.Remove the test cassette from the foil pack.
7.Hold the sample-buffer solution mixing tube upright.
8.Invert the sample-buffer solution mixing tube and transfer 3 full drops of the extracted sample to the sample well (S) of the test cassette, then start the timer.
NOTE: Avoid air bubbles in the sample well (S).
9.Read results 5 minutes after the sample-buffer solution mixture is added to the test cassette. Do not read results after 15 minutes.
NOTE: If the specimen does not migrate on the test cassette (presence of particles), centrifuge the extracted specimens contained in the buffer solution vial. Collect 80µL of supernatant, dispense into the specimen well (S) of a new test cassette and start again following the instructions above.



INTERPRETATION OF TEST RESULTS

Positive: Both purplish test band and purplish control band appear on the membrane.
Negative: Only the purplish control band appears on the membrane. The absence of a test band indicates a negative result.
Invalid: There should always be a purplish control band in the control region regardless of test result. If control band is not seen, the test is considered invalid. Repeat the test using a new test cassette/strip.



QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

PERFORMANCE CHARACTERIST

1. Accuracy

A side-by-side comparison was conducted using the H. Pylori Ag Rapid Test and commercially available H. Pylori Ag test. 938 clinical Specimens from three Professional Point of Care sites were evaluated with the H. Pylori Ag Rapid Test and the commercial kit. The following results are tabulated from these clinical studies.

H. Pylori Ag Rapid Test	Commercial Test		
	Positive (+)	Negative (-)	Total
Positive	297	1	298
Negative	2	258	260
Total	299	259	558
Sensitivity: 99.33%			
Specificity: 99.61%			
Accuracy: 99.46%			

2.Cross Reactivity and Interference

1)Cross reactivity with following organisms has been studied. The following organisms were found negative when tested with the H. Pylori Ag Rapid Test.

Candida albicans	Campylobacter jejuni
Clostridium difficile	Escherichia coli
Escherichia coli	Enterococcus faecalis
Enterobacter aerogenes	Klebsiella pnenmoniae
Proteus vulgaris	Proteus mirabilis
Pseudomonas aeruginosa	Staphylococcus aureus
Salmonella choleraesuis	Salmonella typhi
Salmonella typhimurium	Shigella dysenteriae
Shigella flexneri	Shigella boydii

2)Potentially cross-reactive endogenous substances including common components, such as lipids, hemoglobin, bilirubin, were spiked at high concentrations into the H. pylori antigen positive and negative specimens and tested, separately. No cross reactivity or interference was observed to the test kit.

Analytes	Specimen	
	Positive	Negative
Albumin	+	-
Bilirubin	+	-
Hemoglobin	+	-
Glucose	+	-
Uric Acid	+	-
Lipids	+	-

3) Some other common biological analytes were spiked into the H. pylori antigen positive and negative specimens and tested separately. No significant interference was observed at the levels listed in the table below.

Analytes	Specimen	
	Positive	Negative
Acelaminophen	+	-
Acetoacetic Acid	+	-
Acetylsalicylic Acid	+	-
Benzoylecgonine	+	-
Caffeine	+	-
EDTA	+	-
Ethanol	+	-
Gentisic Acid	+	-
ß – Hydroxybutyrate	+	-
Methanol	+	-
Phenothiazine	+	-
Phenylpropanolamine	+	-
Salicylic Acid	+	-

3. Reproducibility

Reproducibility studies were performed for H. pylori Antigen Rapid Test at three physician office laboratories (POL). Sixty (60) clinical specimens, 20 negative, 20 borderlines positive and 20 positives, were used in this study. Each specimen was run in triplicate for three days at each POL. The intra-assay agreements were >99%. The inter-site agreement was >99%.

LIMITATIONS

1.The H. pylori Ab Rapid Test is for in vitro diagnostic use only. The test should be used for the detection of H. pylori antigen in human feces only. Neither the quantitative value nor the rate of increase in H. Pylori antigen 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.If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended.

SYMBOLS USED

COMPONENT	Material Included
TEST CARD	Test Card
TUBE	Tube
IFU	Instruction for Use
	Consult Instruction for Use
2°C 30°C	Store at 2℃ ~ 30℃
	Expiration Date
	Manufacturer
	Keep Dry
LOT	Lot Number
DILUENT	Sample Buffer
	Date of Manufacture
	Do Not Reuse
REF	Reference Number
	Keep Away from Sunlight
Σ	Tests per Kit
IVD	In Vitro Diagnostic Medical Device
	Do not use if the package is damaged
%40 %60	Store between %40-%60 humidity
CE	This product fulfils the requirements of the Directive 98/79/EC on in vitro diagnostic medical device

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