RapidFor™ H. pylori Ag Test Kit
Reference Number: VMD16
Model: VMD16TD
For Professional use

IVD IFU CE

FOR IN VITRO DIAGNOSTIC USE

These 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 Test Kit 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 Test Kit 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 aid 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 Test Kit 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 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 SUPPLIED MATERIALS

COMPONENT	20 Test/box
Test Device	20 x Test cassettes
Sample Diluent	20 x Sample Diluent (1.5mL)
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 the pouch opens, the test should be used within one hour. Prolonged exposure to hot and humid environments 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.

TEST PROCEDURE

Allow the test, specimen, sample diluent and/or controls to reach room temperature (2-30°C) prior to testing

1. To collect fecal samples:

-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 are 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.

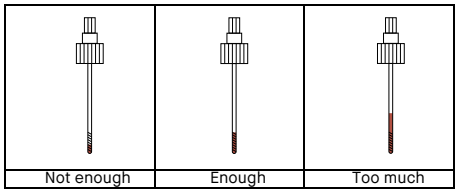
2. To process fecal samples (Figure 1):

- For Solid Samples:

Open the sample collection tube cap, then randomly insert the sample collection applicator into the stool sample at least three different spots to collect approximately 50 mg of stool (equivalent to 1/4 of a pea). Do not scoop the stool sample.

-For Liquid Specimens:

Hold the sample diluent tube vertically, aspirate the liquid feces sample, and then transfer 2 drops (approximately 80 µL) into the sample diluent.

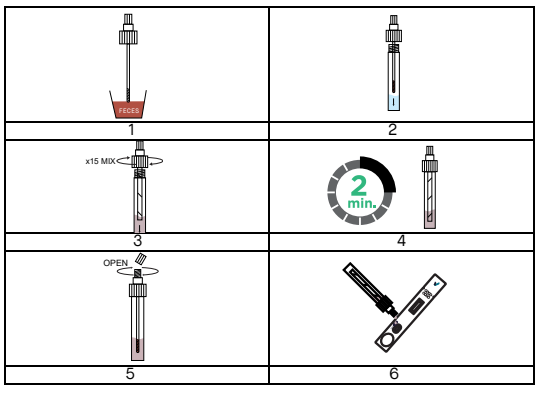


3.Insert the sample collection applicator into the tube containing the sample diluent. (**See Figure 2**)
4.To dissolve the sample in the diluent, rotate the applicator inside the solution 15 times. (**See Figure 3**)
5.Once the sample and the diluent are thoroughly mixed, press the applicator down to close the tube tightly.
Note: Wait 2 minutes to allow the sample to settle in the diluent. (**See Figure 4**)

Test Procedure

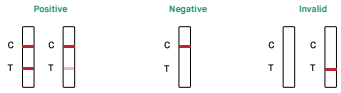
NOTE: Bring the package to room temperature before opening.
NOTE: Do not open the package until you are ready to test, and it is recommended that the disposable test be used within 15 minutes under low ambient humidity (RH≤70%).
NOTE: Best results are obtained if the test is performed immediately after opening the foil pack.
6. Remove the test cassette from the foil pouch.
7. Hold the sample diluent tube upright and open the cap of the sample collection tube. (**See Figure 5**)
8.Invert the sample diluent tube and dispense exactly 3 full drops of the extracted sample into the sample well (S) of the test cassette, then start the timer.
(See Figure 6)
NOTE: Avoid leaving air bubbles in the sample well (S).
9.Read the results 15 minutes after adding the sample–sample diluent mixture to the test cassette. Do not read the results after 20 minutes.
NOTE: If the sample does not migrate across the test cassette (due to the presence of particulates), centrifuge the extracted sample in the sample diluent tube.Collect 80 µL of the supernatant and dispense it into the sample well (S) of a new test cassette.

Restart the procedure 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 the control band is not seen; the test is considered invalid. Repeat the test using a new test cassette.



QUALITY CONTROL

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 Test Kit and commercially available H. Pylori Ag test. 938 clinical Specimens from three Professional Point of Care sites were evaluated with the H. pylori Ag Test Kitand the commercial kit. The following results are tabulated from these clinical studies.

H. Pylori Ag Rapid Test	Commercial Test		
	Positive (+)	Negative (-)	Total
Positive	413	4	417
Negative	8	513	521
Total	421	517	938
Sensitivity: 98.10%			
Specificity: 99.23%			
Accuracy: 98.72%			

2.Cross Reactivity and Interference

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

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	+	-

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
	Store at 2℃ ~ 30℃
	Expiration Date
	Manufacturer
	Keep Dry
LOT	Lot Number
DILUENT	Sample Diluent
	Date of Manufacture
	Do Not Reuse
REF	Reference Number
	Keep Away from Sunlight
	Tests per Kit
IVD	In Vitro Diagnostic Medical Device
	Do not use if the package is damaged
	Store between %40-%60 humidity
CE	This product fulfils the requirements of the Directive 98/79/EC on in vitro diagnostic medical device

VITROSENS

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