H.Pylori Antigen Rapid Test Device
Package Insert

For detection of H.Pylori Antigens in Human Stool Specimens.
For professional in vitro diagnostic use only.

INTENDED USE

The H.pylori Antigen Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of H.pylori antigen in feces.

SUMMARY

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 a further evidence.H.pylori Antigen Rapid Test Device is a simple, visual qualitative test that detects H.pylori antigen in feces.

PRINCIPLE

The H.pylori Antigen Rapid Test Device is a qualitative membrane strip based immunoassay for the detection of H.pylori antigen in 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.

REAGENTS

The test contains H.pylori antibody particles and H.pylori antibody coated on the membrane.

PRECAUTIONS

1. For in vitro diagnostic use only.DO NOT RE-USE test device
2. The instructions must be followed to obtain accurate results.Anyone performing an assay with this product must be trained in its use and laboratory procedures.
3. Do not eat or smoke while handling specimens
4. Wear protective gloves while handling specimens.Wash hands thoroughly afterwards.
5. Avoid splashing or aerosol formation
6. Clean up spills thoroughly using an appropriate disinfectant
7. Decontaminate and dispose of all specimens,reaction kits and potentially contaminated materials,as if they were infectious waste,in a biohazard container.
8. Do not mix with other specimens.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C).The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

1. The H.pylori Antigen Rapid Test Device can be performed used on feces.
2. Collect sufficient quantity of 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.
3. Specimen collected may be stored for 3 days at 2-8℃ if not tested within 6 hours. For long term storage, specimens should be kept below -20℃.
4. Unscrew the cap of the specimen collection tube,then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea).Do not scoop the fecal specimen.
5. 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.
6. 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.

MATERIALS

Materials provided

- Test Device
- Specimen collection tubes with extraction buffer
- Package insert

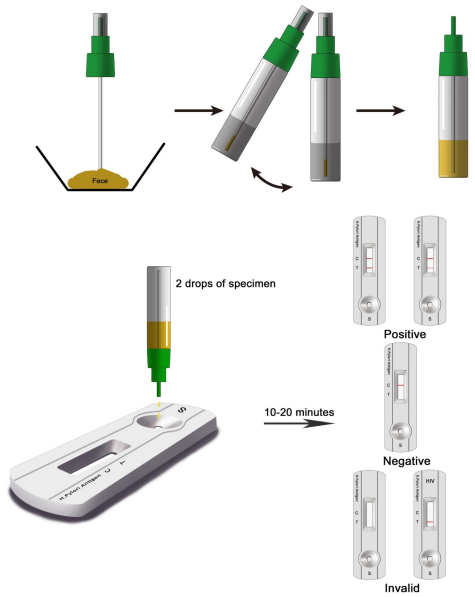
Materials required but not provided

- Timer
- Specimen collection containers

DIRECTIONS FOR USE

Allow the test, specimen and/or controls to reach room temperature 15-30℃prior to testing.

1. Bring the pouch to room temperature before opening it.Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface.
3. Holding the sample collection tube upright,carefully take off the tip of collection tube,**transfer 2 drops (approximately 100μl)** to the specimen well(S) of the test device,then start the timer.See illustration below.
4. Wait for the colored line(s) to appear.**Read results at 10 minutes.**Do not interpret the result after 20 minutes.



Notes:
Applying sufficient amount of specimen is essential for a valid test result.If migration (the wetting of membrane) is not observed in the test window after one minute,add one more drop of specimen to the specimen well.

INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:* Two distinct colored lines appear.One line should be in the control line region (C) and another line should be in the test line region (T).

***NOTE:**The intensity of color in the test line region (T) will vary depending on the concentration of H.p antigen present in the specimen. Therefore, any shade in the test region indicates positive result.

NEGATIVE:One colored line appears in the control line region (C). No apparent colored line appears in the test line region (T).

INVALID: No line appears in the control line region (C). If this occurs, read the directions again and repeat the test with a new test. If the result is still invalid, stop using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The H.pylori Antigen Rapid Test Device is for in vitro diagnostic use only.The test should be used for the detection of H.pylori antigen in feces only. Neither the quantitative value nor the rate of increase in H.pylori antigen can be determined by this qualitative test.
2. The H.pylori Antigen Rapid Test Device will only indicate the presence of H.pylori antigen in the specimen and should not be used as the sole criteria for the diagnosis of H.pylori antigen.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. 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 H.pylori infection with caution during antibiotic treatment.

QUALITY CONTROL

A procedural control is included in the test.A colored line appearing in the control line region (C) is considered an internal procedural control.
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.

EXPECTED VALUES

The H.pylori Antigen Rapid Test Device has been compared with Endoscope-based methods, demonstrating an overall accuracy of 98.9 %.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The H.pylori Antigen Rapid Test Device has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals.The result shows that the sensitivity of the H.pylori Antigen Rapid Test Device is >99.9 % and the specificity is 98.1% relative to Endoscope .

Method		Endoscope-based method		Total Result
H.pylori Antigen Rapid Test Device	Result	Positive	Negative	
	Positive	78	2	80
	Negative	0	101	101
Total Result		78	103	181

Relative sensitivity:78/78＞99.9 % (95% CI " : 96.2 % -100.0%) ;
Relative specificity:101/103=98.1% (95% CI " :93.2 % -99.8%)
Accuracy: (78+101)/ (78+103) = 98.9 % (95%CI: 96.1 % -99.9%)
CI" : Confidence Intervals

Precision Intra- Assay

Within-run precision has been determined by using 15 replicates of four specimens: negative, low positive, middle titer positive and high titer positive specimens. The specimens were correctly identified > 99 % of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same four specimen negative, low titer positive, middle titer positive and high titer positive specimens. Three different lot the H.pylori Antigen Rapid Test Device have been tested using these specimens. The specimen were correctly identified > 99 % of the time.

Cross-reactivity

Cross reactivity with following organisms has been studied at 1.0E9 organisms/ml. The follow organisms were found negative when tested with the H.pylori Antigen Rapid Test Device.

Acinetobacter spp	Enterococcus faecalis	Group A Streptococcus
Candida albicans	Acinetobacter calcoaceticus	Proteus mirabilis
Chlamydia trachomatis	Klebsiella pneumonia	Group B Streptococcus
Branhamella catarrhalis	E.coli	Gardnerella vaginalis
Group C Streptococcus	Rotavirus	Adenovirus
Neisseria meningitides	Pseudomonas aeruginosa	Staphylococcus aureus
Neisseria gonorrhea	Proteus vulgaris Salmonella choleraesius	

BIBLIOGRAPHY

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3. (1990),322: 909-16 of bacterial colonization and gastritis.Amer.J.Gastroenterology. (1987), 82(4):292-96.41S individual with Helicobacter pylori infection.Am J Gastroenterol. 1996,91:1112-1115.

SYMBOLS

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community /European Union
	Date of Manufacture		Use-by date
	Do not re-use		Consult instructions for use or consult electronic instructions for use
LOT	Batch code		Do not use if package is damaged and consult instructions for use
REF	Catalogue number		Contains sufficient for <n> tests

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