

# H. Pylori Ag Rapid Test

For detection of *H. Pylori Antigen* in Human Stool Specimens.



In-vitro diagnostic use only



Not reuse

## Introduction

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. One step H.pylori Ag Test is a simple, visual qualitative test that detects H.pylori antigen in feces. The test is based on immunochromatography and can give a result within 15 minutes.

## Intended Use

The One Step H.pylori Ag Test is a rapid chromatographic immunoassay for the qualitative detection of H.pylori antigen in feces.

## Principle

The One Step H.pylori Ag Test 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.

## Materials Included and Active Ingredients

### Materials Provided

- Test devices
- Buffer
- Disposable specimen droppers
- Package insert

### Materials Required But Not Provided

- Timer
- Specimen collection containers
- Centrifuge

## Kit Precautions and Storage Instructions

- 1) For best results, adhere to instructions provided
- 2) All specimens should be handled as potentially infectious

- 3) The test device should be stored at room temperature
- 4) The test device is sensitive to humidity as well as heat
- 5) Do not use beyond expiration date
- 6) Do not use test kit if pouch is damaged or seal is broken
- 7) Use test device immediately after removing from the pouch
- 8) The components (test device and assay diluents) in this kit have been quality control tested as a standard batch unit. Do not mix components from different lot numbers.
- 9) Store kit at room temperature (2 -30 °C). Do not expose the kit to temperature over 30 °C.

## Warnings

- 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.

## Specimen Collection, Storage and Precautions

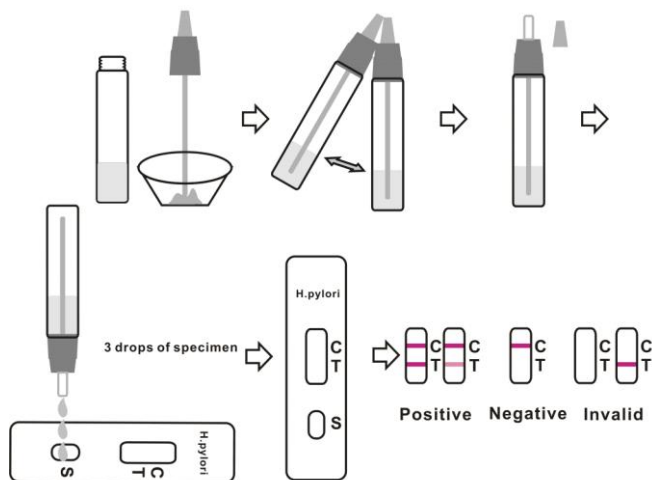
1. The One Step H.pylori Ag Test can be performed used on feces.
2. Collect sufficient quantity of feces (1-2 ml or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assays performed within 6 hours after collection.
3. Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours. For long term storage, specimens should be kept below -20°C.
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.

## Test Procedure (Refer to Figure)

Allow the test, specimen and/or controls to reach room temperature 15-30°C (59-86°F) 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 3 drops (approximately 100 µl) to the specimen well(S) of the test device, then start the timer. See illustration below.

- Wait for the colored line(s) to appear. Read results at 15 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 Test Results (Refer to Figure)

##### 1) Negative

The control line is the only visible line on the test device. This indicates a negative result.

##### 2) Positive

The presence of two color lines ("T" line and "C" line) within the result window, no matter which line appears first, indicates a positive result.

##### 3) Invalid

If the "C" line (control) is not visible within the result window after performing the test, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.

#### Limitations of the Test

- The One Step H.pylori Ag Test 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.
- The One Step H.pylori Ag Test 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.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

- 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.

#### Internal Quality Control

There is a "Test line" and a "Control line" on the surface of *H. pylori* Ag Rapid Test device cassette. Both the Test Line and Control Line in the result window are not visible before applying any samples. The Control Line is used for procedural control. The Control line should always appear if the test procedure is performed properly and the test reagents of the control line are working.

#### Expected value

*H. pylori* infections occur in human populations throughout the world, but the prevalence of infection in the population varies with age, standards of hygiene, geographical regions, and probably socioeconomic status. 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. People in developing countries tend to have higher prevalence.

**REF** RT-HP1102-C-1

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