H.PYLORI ANTIGEN

IMMUNOPAK

(Stool)

Last update 10-2020

Ref. RDT-HPY.116, 25 Test

INTENDED USE

The H.Pylori Antigen Card 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.

INTRODUCTION

H.pylori is associated with a variety of gastrointestinal diseases included non-ulcer dyspepsia, duodenal and gastric ulcer 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 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.

PRINCIPLE

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

PRESENTATION

	25 Tests
H.pylori Antigen Card Test	25 Cards
Sample Collection Tubes with Buffer	25 tubes

PRECAUTION

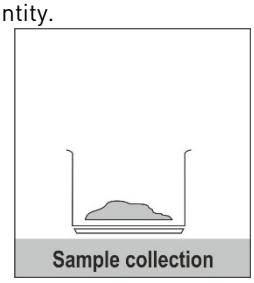
- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as if they contain infectious agents.
- Observe established precautions against microbiological hazards throughout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

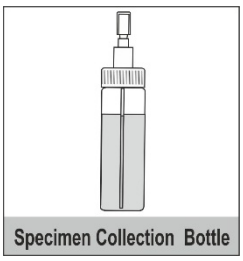
STORAGE & STABILITY

- Store as packaged in the sealed pouch at room temperature 2°C-40°C. The kit is stable within the expiration date printed on the labeling.
- Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.

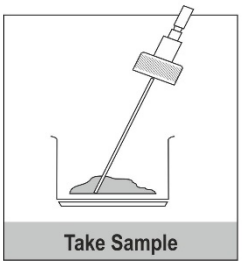
SPECIMEN COLLECTION AND STORAGE

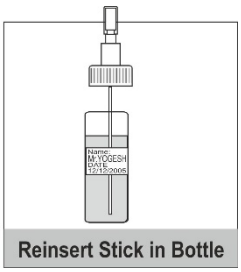
1. Use human feces as specimen.
2. Collect sufficient quantity of feces (1-2 ml or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assays performed within 6 hours after collection.
3. Specimen collected may be stored for 3 days at 2°C-8°C if not tested within 6 hours. For long term storage specimens should be kept below -20°C
4. Refrigerated specimens must be brought to room temperature prior to testing.
5. Label the specimen collection bottle with specimen identity.





6. 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 ¼ of a pea). Do not scoop the fecal specimen.
7. Take representative amounts of feces specimen from different portions of the sample by introducing the sampling stick at least 5 different places in the feces specimen.
8. Wipe the sampling stick with an absorbent or tissue paper. The sample taken up by the grooves is sufficient for the test.





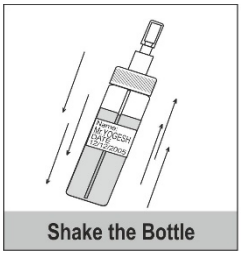
9. Reinsert the sampling stick into the bottle and screw the cap tightly.
10. Shake the specimen collection bottle so that there is proper homogenisation of feces in buffer solution. Leave the tube alone for 2 minutes.

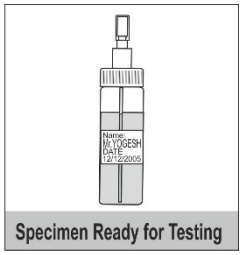
H.PYLORI ANTIGEN

(Stool)

IMMUNOPAK

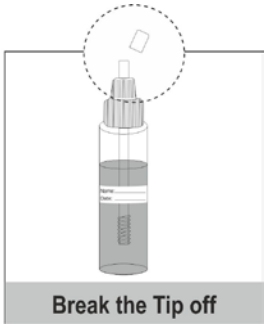
Last update 10-2020





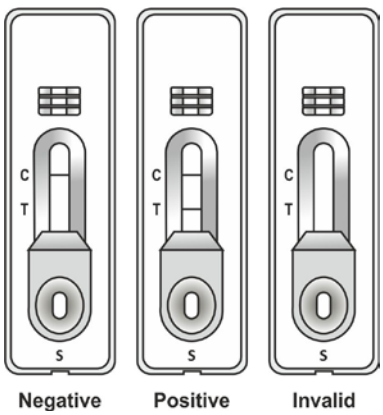
TEST PROCEDURE

1. Bring the kit components of device to room temperature prior to testing.
2. Open a foil pouch by tearing along the "notch".
3. Remove the testing device. Once opened, the device must be used immediately.
4. Place the testing device on a flat horizontal surface.
5. Hold the specimen collection bottle in an upward position and break the tip off, transfer 3 drops (approximately 100 µl) to the specimen well of the test device, then start the timer. See illustration below.
6. Read results at 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

- **Negative:** Only one pink-purple line appears on the control (C) region. No apparent line on the test (T) region.
- **Positive:** In addition to a pink-purple control (C) line, a distinct pink-purple line will also appear in the test (T) region.
- **Invalid:** A total absence of pink-purple line in both regions or no pink-purple line appears on the control (C) region is an indication of procedure error and / or the test regent deterioration. Repeat the test with a new test cassette.



LIMITATIONS

- The H.pylori Antigen 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.
- 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.

PERFORMANCE CHARACTERISTICS

Cross Reactivity and Interference

1. 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	Conc.	Specimens	
		Positive	Negative
Albumin	20mg/ml	+	-
Bilirubin	10µg/ml	+	-
Hemoglobin	15mg/ml	+	-
Glucose	20mg/ml	+	-
Uric Acid	200µg/ml	+	-
Lipids	20mg/ml	+	-

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

Analytes	Conc. (µg/ml)	Specimens	
		Positive	Negative
Acetaminophen	200	+	-
Acetoacetic Acid	20	+	-
Acetylsalicylic Acid	200	+	-
Benzoylecgonine	100	+	-
Caffeine	200	+	-
EDTA	800	+	-
Ethanol	1.0%	+	-
Gentisic Acid	200	+	-
ß – Hydroxybutyrate	20.0	+	-
Methanol	10.0%	+	-
Phenothiazine	200	+	-
Phenylpropanolamine	200	+	-
Salicylic Acid	200	+	-

REFERENCES

1. Soll, AH. Pathogensis of peptic ulcer and implications for therapy. New England J. Med. (1990), 322: 909-16.
2. Hazell,SL, et al. Campylobacter pyloridis and gastritis I: Detection of urease as a marker of bacterial colonization and gastritis. Amer. J. Gastroenterology (1987), 82(4():292-96.
3. Cutler AF. Testing for Helicobacter pylori in clinical practice. Am J. Med. 1996; 100:35S-41S.
4. Anand BS, Raed AK, Malaty HM, et al, Loe point prevalence of peptic ulcer in normal individual with Helicobacter pylori infection. Am J Gastroenterol. 1996,91:1112-1115.

Regd. Office.3/7, B.I.D.C., Gorwa, Vadodara 390 016 (INDIA)
Web: www.reckondiagnostics.com Ph: +91·265·2281631
Email: mail@reckondiagnostics.com
An ISO 13485:2016 & GMP Certified Company

RECKON DIAGNOSTICS P. LTD.
THE TEST OF CONFIDENCE - SINCE 1989