H. pylori Ag Rapid Test (Cassette) (Feces)

For professional *in vitro* diagnostic use only.

INTENDED USE

The H. pylori Rapid Test Device (Feces) is a rapid chromatographic immunoassay for the qualitative detection of antigens to H. pylori in feces to aid in the diagnosis of H. pylori infection.

INTRODUCTION

H.Pylori Stool Card is a screening immunochromatographic assay to detect Helicobacter pylori antigen in stool samples.
Helicobacter pylori (also known as Campylobacter pylori) is a spiral-shaped with a typical flagellum, Gram negative bacteria, infecting gastric mucosa. It causes several gastro-enteric diseases such as non-ulcerous dyspepsia, gastric and duodenal ulcer, active gastritis and can even increase the risk of stomach adenocarcinoma, so as to be classified as carcinogen agent type I.
Many H. pylori strains have been isolated: among them, the strain expressing CagA antigen is strongly immunogenic and, according to this, it is of utmost clinical importance because it is associated to the cytotoxic factor. It is widely reported in many literature articles that, in infected patients showing antibodies against CagA gene product, the risk of gastric cancer is up to five times higher than the reference group infected with a CagA negative bacterial strain.
The presence of the gene itself determines the persistence of the infection, the ulceration and the protein associated, VacA toxin is frequently the main cause of infiltrations in the gastric mucosa.
This antigen associated to others, such as CagII, CagC, seems to act as starting agent of a sudden inflammatory response which can provoke ulceration (peptic ulcer), allergic episodes, and a decrease of the therapy efficacy.
At present several invasive and non-invasive approaches are available to detect this infection state.
Invasive methodologies requires endoscopy of the gastric mucosa with a histologic, cultural and urease investigation, which are cost-effective and requiring long times to come to a correct final diagnosis.
Alternatively, non-invasive methods are available such as Breath Test, which is extremely complicated and not highly selective, or classical ELISA and immunoblotting assays.

PRINCIPLE

H.Pylori Stool Card is a non-invasive lateral flow assay, rapid, precise and easy to perform.

This test makes use of specific antibodies against H. pylori antigen adsorbed onto a reactive membrane. If H. pylori is present in stool specimen, the specific antigen is bound by the second antibody which is conjugated with colloidal gold particles. A generic antibody, fixed onto the reactive membrane, in shape of the band, is able to capture the second conjugated antibody, assuring the correctness of the test performance.

KIT COMPONENTS

Individually packed test devices	Each device contains a strip with colored conjugates and reactive reagents pre-spreaded at the corresponding regions.
Tubes with buffer	2mL/vial. Phosphate buffered saline and preservative, extract the samples
Package insert	For operation instruction.

MATERIALS REQUIRED BUT NOT PROVIDED

Specimen collection container	For specimens collection use.
Timer	For timing use.
Centrifuge	For preparation of clear specimens

PRECAUTIONS

- For in-vitro diagnostic use only
- For professional use only
- Use the test device only once
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Do not use test kit after expiration date
- Do not mix Sample Collection Tubes from different lots.
- Do not open the Test Cassette foil pouch until you are ready to perform the test.
- Do not spill solution into the reaction zone
- Do not touch the reaction zone of the device to avoid contamination
- Avoid cross-contamination of samples by using a new specimen collec¬tion container and specimen collection tube for each sample.
- All patient samples should be treated as if capable of transmitting disease. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Do not use more than the required amount of liquid.
- Bring all reagents to room temperature (15-30°C) before use.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Buffered Saline contains sodium azides which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of buffered saline or extracted samples, always flush with copious quantities of water to prevent azide build up.
- Evaluate the test result after 10 minutes and not beyond 20 minutes.
- Store and transport the test device always at 2-30°C (36°-86°F)
- Humidity and high temperature can adversely affect results.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- Patients should not collect samples during their menstrual period, if they have bleeding hemorrhoids, blood in the urine, or if they have strained during bowel movement.
- Collect a random sample of feces in a clean dry container or receptacle.
- Unscrew and remove the collection tube applicator stick. Be careful not to spill or spatter solution from container.
- Collect random sample by using the applicator stick. Take sample from various surfaces of the feces specimen from 3 points.
- Re-insert the applicator stick into the tube and screw the cap tightly. Be careful not to break the tip of the Sample Collection Tube.
- The diluted sample must be tested in 30 minutes, otherwise the results would be not correct.

PROCEDURE

Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.

1. Specimen collection and pre-treatment:
   1) Unscrew and remove the dilution tube applicator. Be careful not to spill or spatter solution from the tube. Collect specimens by inserting the applicator stick into at least 3 different sites of the feces.
   2) Place the applicator back into the tube and screw the cap tightly. Be careful not to break the tip of the dilution tube.
   3) Shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Specimens prepared in the specimen collection tube may be stored for 6 months at -20°C if not tested within 1 hour after preparation.
2. Testing
   1) Remove the test from its sealed pouch, and place it on a clean, level surface. Label the test with patient or control identification. To obtain a best result, the assay should be performed within one hour.
   2) Using a piece of tissue paper, break the tip of the dilution tube. Hold the tube vertically and dispense 3 drops of solution into the specimen well (S) of the test device.
      Avoid trapping air bubbles in the specimen well (S), and do not drop any solution in observation window.
      As the test begins to work, you will see color move across the membrane.
3. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS

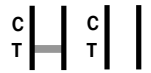
POSITIVE RESULT:

Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE RESULT:

Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

INVALID RESULT:



Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level can not be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. 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.

LIMITATIONS OF THE TEST

1. The H. pylori Rapid Test Device (Feces) is for in vitro diagnostic use only. The test should be used for the detection of H. pylori antigens infeces only. Neither the quantitative value nor the rate of increase in H. pylori antigen concentration can be determined by this qualitative test.
2. The H. pylori Rapid Test Device (Feces) will only indicate the presence of H. pylori antigens in the specimen and should not be used as the sole criteria for the diagnosis of H. pylori infection.
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.

PERFORMANCE CHARACTERISTICS

Table: H. pylori Rapid Test vs. Biopsy/Histology/RUT

Relative Sensitivity: >95.0% (90.0%-97.9%)*
Relative Specificity: >95.7% (92.3%-97.9%)*
Overall Agreement: >95.4% (92.8%-97.3%)*
***95% Confidence Interval**

		H. pylori Rapid Test		
		+	-	Total
Biopsy/ Histology/ RUT	+	131	7	138
	-	10	225	235
		141	232	373

LITERATURE REFERENCES

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