CE

IVD

Rapid-VIDITEST

H. pylori Card

One step H. Pylori Card test for the qualitative detection of Helicobacter pylori in faeces.

Instruction manual

INTENDED USE:

The Rapid-VIDITEST *H. pylori* Card is a one step coloured chromatographic immunoassay for the qualitative detection of *H. pylori* in faeces.

INTRODUCTION:

Helicobacter pylori (*H. pylori*) is a spiral-shaped bacterium that is found in the gastric mucous layer or adherent to the epithelial lining of the stomach. *H. pylori* causes more than 90% of duodenal ulcers and up to 80% of gastric ulcers. The importance of *Helicobacter pylori* testing has increased greatly since the strong correlation between the presence of bacteria and confirmed gastrointestinal diseases (stomach and duodenum) like gastritis, peptic ulcer disease and gastric carcinoma.

PRINCIPLE:

The Rapid-VIDITEST *H. pylori* Card is a qualitative immunochromatographic assay for the determination of *Helicobacter pylori* in faeces samples. The membrane is pre-coated with monoclonal antibodies, on the test band region, against *H. pylori* antigens. During testing, the sample is allowed to react with the coloured conjugate (anti-*H. pylori* monoclonal antibodies-red polystyrene microspheres) which was pre-dried on the test strip.The mixture then moves up ward on the membrane by capillary action. As the sample flows through the test membrane, the coloured particles migrate. In the case of a positive result the specific antibodies present on the membrane will capture the coloured conjugate. The mixture continues to move across the membrane to the immobilized antibody placed in the control band region, a red coloured band always appears.
The presence of this red band serves as 1)verification that sufficient volume is added, 2) that proper flow is obtained and 3) as an internal control for the reagents.

MATERALS PROVIDED:

- Rapid-VIDITEST *H. pylori* Card tests
- Instructions for use
- Specimen collection vial with buffer

MATERIALS REQUIRED BUT NO PROVIDED:

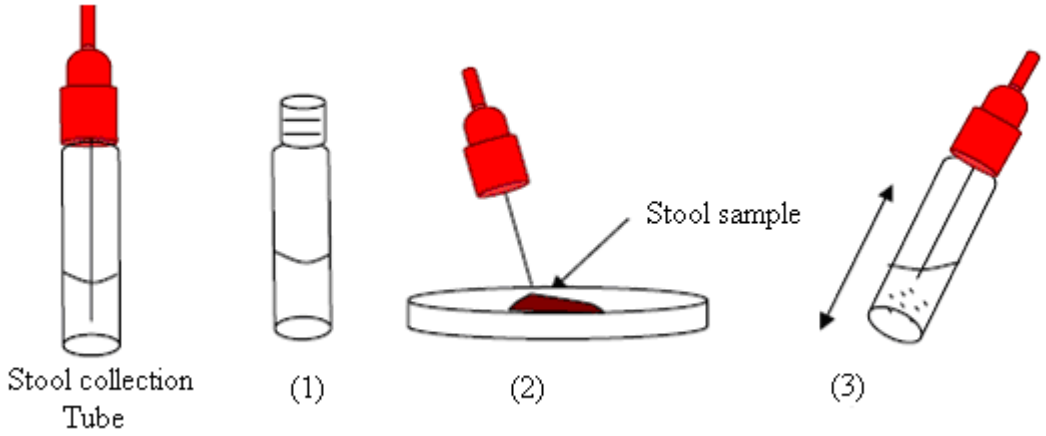
- Specimen collection container
- Disposable gloves
- Timer

SPECIMEN COLLECTION AND PREPARATION:

Stool samples should be collected in clean containers and the assay should be done right after collection. The samples can be stored in the refrigerator (2-4 ºC) for 1-2 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen at –20ºC. In this case, the sample will be totally thawed, and brought to room temperature before testing.

Specimen preparation:

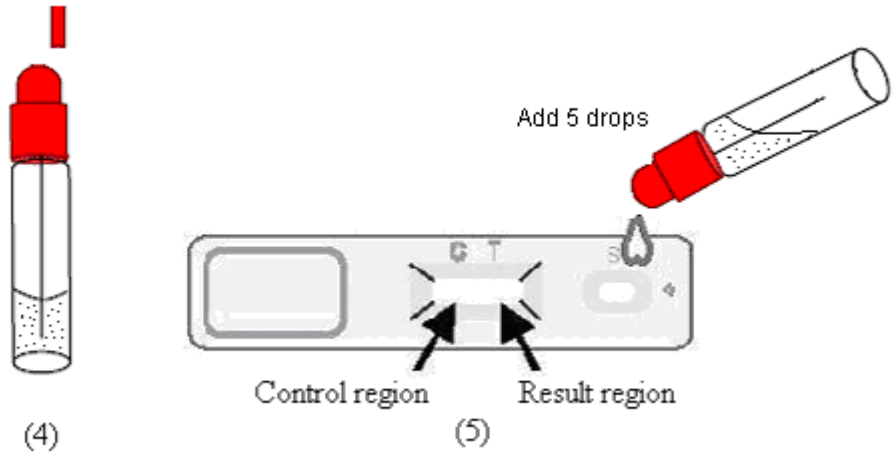
1. Take out the top of the stool collection tube (1) and use the stick to pick up enough quantity of sample (approx. 250 mg) (2). Add the sample into the stool collection tube.
2. Close the tube with the diluent and stool sample. Shake the tube in order to assure good sample dispersion (3).



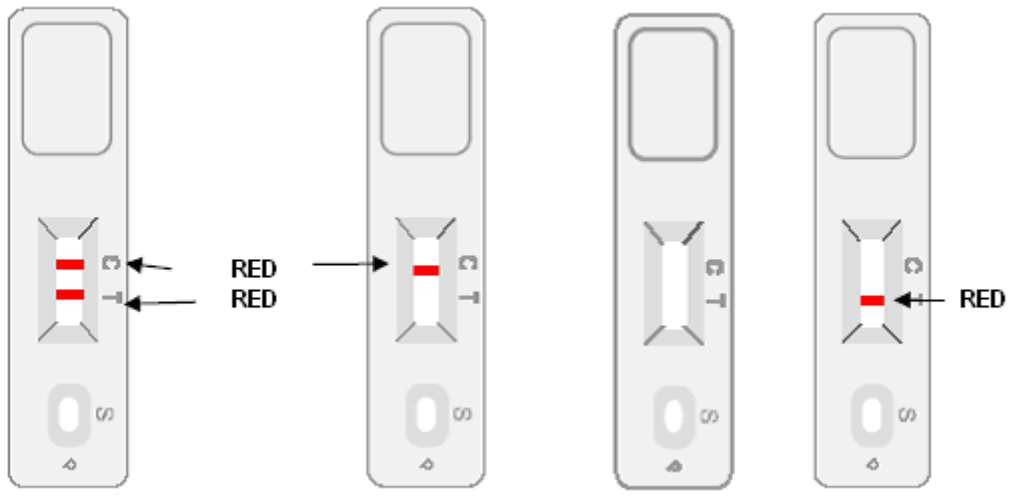
PROCEDURES:

Allow the tests, stool samples and buffer to reach to room temperature (15-30ºC/59-86ºF) prior to testing. Do not open the pouch until ready to perform the assay. Only bring to room temperature the number of tests required to assay before opening it.

1. Remove the Rapid-VIDITEST *H. pylori* Card from its sealed pouch and use it as soon as possible.
2. Shake the specimen collection vial to assure a good sample dispersion. Break off the cap of the vial (4).
3. Use a separate device for each sample. Dispense exactly 5 drops into the specimen well (S) (5). Start the timer.
4. Read the result at **10 minutes** after dispensing the sample.



INTERPRETATION OF RESULTS:



POSITIVE ***NEGATIVE*** ***INVALID***

POSITIVE: Two lines appears across the central window in the result line region, a **red** test line marked with the letter T and in the control line region, a **red** control line marked with the letter C.

NEGATIVE: Only one **red** band (control line) appears across the control line region marked with the letter C.

INVALID: A total absence of the control coloured band regardless of the appearance or not ofthe result line (**red**). Note: Insufficient specimen volume, incorrect procedural echniques or deterioration of the reagents are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit and contact you local distributor.

NOTES ON THE INTERPRETATION OF RESULTS:

The intensity of the red coloured band in the result line region (T) will vary depending on the concentration of antigens in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

QUALITY CONTROL:

Internal procedural controls are included in the test. A red line appearing in the control region is an internal control. It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS:

1. The test must be carried out within 2 hours of opening the sealed bag.
2. An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
3. Some watery and diarrhoeal stool samples can decrease the intensity of the lines.
4. This test provides a presumptive diagnosis of *Helicobacter pylori* infections. A confirmed infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated must be based in the correlation of the results with further clinical observations.

EXPECTED VALUES:

Studies have found that more than 90% of patients with duodenal ulcer and 80% of patients with gastric ulcer are infected with *H. pylori*. The Rapid-VIDITEST *H. pylori* Card has been compared with different methods: cultures, Urea Breath Test and Urease Test, demonstrating an overall accuracy of >92%.

PERFORMANCE CHARACTERISTICS:

Sensitivity and specificity

It was studied some patients with the same as *H. pylori* infection symptoms. For all patient, it was performed an evaluation using Rapid-VIDITEST *H. pylori* Card and a commercial available ELISA *H. pylori* assay to detect *H. pylori* infection.
Rapid-VIDITEST *H. pylori* Card showed >94% of sensitivity and >99% of specificity.

The use of a mouse monoclonal antibody in Rapid-VIDITEST *H. pylori* Card assures high degree of specificity for the detection of this bacteria. The antibodies used to elaborate the Rapid-VIDITEST *H. pylori* Card recognise epitopes present in the antigen found in stool of patients, as well as in preparations from the bacteria cultures in vitro. Sonicated *Helicobacter pylori* extract from different commercial samples reacts with Rapid-VIDITEST *H. pylori* Card.

STORAGE AND STABILITY:

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC/36-86ºF). 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.

PRECAUTIONS:

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- Do not use the test if pouch is damaged.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test should be discarded in a proper biohazard container after testing.
- The test must be carried out within 2 hours of opening the sealed bag.

REFERENCES:

1. Bruce E. Dunn, Hartley Cohen, Martin J. Blaser. *Helicobacter pylori.* Clin.Microbiol.Rev.10(4), 720-741, Oct.(1997).
2. Martin J. Blaser. *Helicobacter pylori and gastric diseases.* BMJ; 316;, 1507-1510 (1998).
3. John L. Telford, Antonello Covacci, Rino Rappuoli, Paolo Ghiara. *Immunobiology of Helicobacter pylori infections.* Current Opinion in Immunology, 9, 498-503 (1997).

SYMBOLS FOR IVD COMPONENTS AND REAGENTS:

IVD	*In vitro* diagnostic device	LOT	Batch code
	Use by		Manufacturer

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