CE

IVD

Rapid-VIDITEST

H. pylori Blister

One step Helicobacter pylori Blister test.

Instruction manual

INTENDED USE:

The Rapid-VIDITEST *H. pylori* Blister 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* Blister 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 micro spheres) which was pre-dried on the test strip. The mixture then moves upward 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 kontrol 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* Blister tests
- Instructions for use
- Stool collection tubes with sample diluent

MATERIALS REQUIRED BUT NO PROVIDED:

- Specimen collection container
- Testing tubes or vials
- Disposable gloves
- Timer

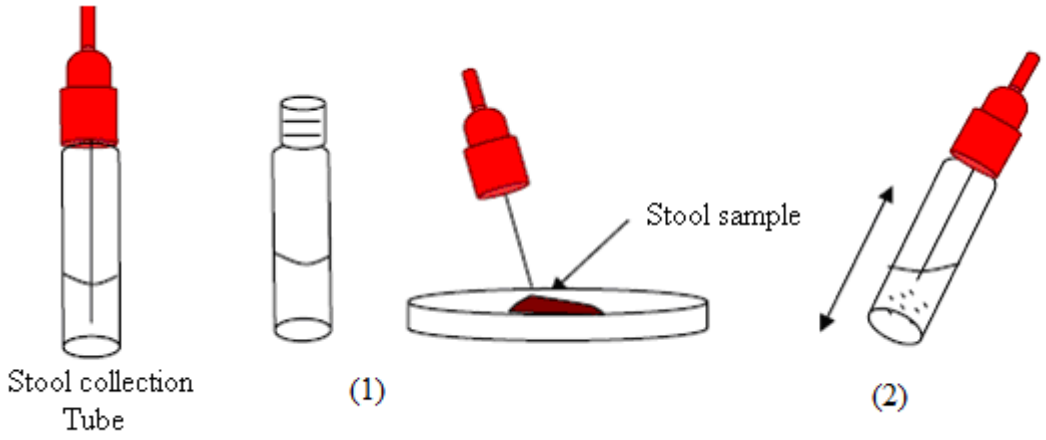
SPECIMEN COLLECTION AND PREPARATION:

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.

PROCEDURES:

Specimen preparation:

(1) Take out the top of the stool collection tube and use the stick to pick up enough quantity of sample (approx. 250 mg). 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.



Test Procedure:

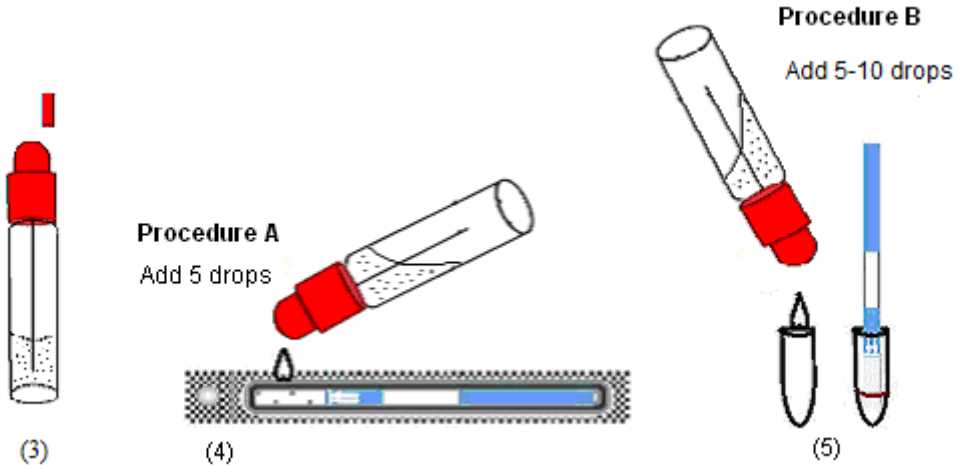
Allow the test, stool samples and controls to reach to room temperature (15-30ºC) prior to testing. Do not open the package until ready to perform the assay. Only bring to room temperature the number of tests required to assay before opening it. There are two possibilities for performing the test.

A) Using the blister Test single pack as a Card test:

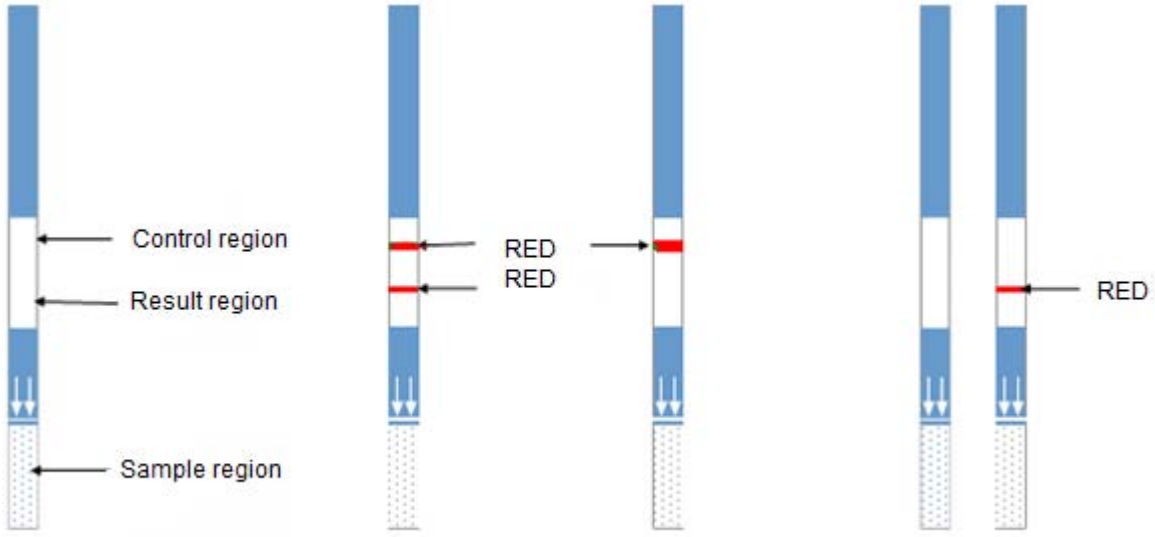
1. Cut the blister to obtain a test single pack, hold the non sealed side and open it peeling off the upper foil. Don't remove the test from the blister cavity and use it as soon as possible.
2. Proceed to shake the stool collection tube in order to assure good sample dispersion. Cut the end of the top (3).
3. Place blister test single pack horizontally. Dispense exactly 5 drops or 150 µL on the white end of the test (4). Use a separate stool collector tube and device for each sample or control.
   Read the result at 10 minutes without further manipulation.

B) Using the blister Test single pack as a Strip test: By immersion:

1. Cut the blister to obtain a test single pack, hold the non sealed side and open it peeling off the upper foil.
2. Proceed to shake the stool collection tube in order to assure good sample dispersion. Cut the end of the top (3).
3. Dispense 10 drops of the sample diluent in a testing tube or vial (5). Place the Rapid-VIDITEST *H. pylori* Blister Test vertically with the white end submerged into the sample taking care of not surpassing the limit of immersion indicated with the arrows. **Read the result at 10 minutes** without further manipulation.



INTERPRETATION OF RESULTS:



Blister Test POSITIVE NEGATIVE INVALID

NEGATIVE: Only one RED band (control line) appears in the white central zone of the test (control region).

POSITIVE: In addition to the RED control band, another distinguishable RED band (result line) also appears in the white central zone of the test (result region).

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

NOTES ON THE INTERPRETATION OF RESULTS:

The intensity of the red coloured band in the test line region 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.

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* Blister and a commercial available ELISA *H. pylori* assay to detect *H. pylori* infection. The results are showed:

	EIA Test	
	Sensitivity	Specificity
Rapid-VIDITEST *H. pylori* Blister	>94%	>99%

The use of a mouse monoclonal antibody in Rapid-VIDITEST *H. pylori* Blister assures high degree of specificity for the detection of this bacteria. The antibodies used to elaborate the Rapid-VIDITEST *H. pylori* Blister 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* Blister.

STORAGE AND STABILITY:

Store as packaged in the blister at 2-30ºC. The test is stable through the expiration date printed on each blister. The test must remain in the closed pack until use. Do not freeze.

PRECAUTIONS:

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date.
- 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.

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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