HELICOBACTER PYLORI FECAL

One step – Cassette

IVD

One Step for the qualitative detection of *Helicobacter pylori (H. pylori)* in faeces

PACKAGING

Ref.: 101-0699	Cont.: 20 tests

Store at 2-30º C

INTENDED USE

The *Helicobacter pylori* Fecal Test is a rapid coloured chromatographic, for health care professional use only. It is intended for use at point of care facilities for the qualitative detection of *H. pylori* in faeces.

This assay provides only a preliminary result. Clinical consideration and professional judgment must be applied, particularly when preliminary positive results are evaluated. A more specific alternate method must be used in order to obtain a confirmed analytical result.

CLINICAL SIGNIFICANCE

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* Antigen 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 OF THE METHOD

This assay is a chromatographic immunoassay. The membrane is pre-coated, on the test band region, with monoclonal antibodies 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 moving across the membrane to the immobilized antibody placed in the control band region, where a red coloured band should always appears. The presence of this red band is used as 1) verification that sufficient volume is added, 2) that proper flow is obtained and 3) as an internal control for the reagents.

MATERIALS SUPLLIED

Ref.101-0699 20 test devices and 20 stool collection tubes with sample diluent

MATERIAL REQUIRED BUT NOT PROVIDED

- Specimen collection containers
- Timer
- Disposable gloves

STORAGE AND STABILITY

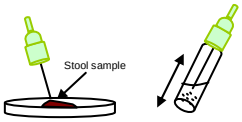
Store as packaged in the sealed pouch at 2-30º C. The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze.

SPECIMEN COLLECTION

Stool samples (not watery and diarrhoeal) should be collected in clean containers and the assay should be done right after collection. The samples can be stored in the refrigerator (2-4º C) for 1-2 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen at –20º C. In this case, the sample will be totally thawed, and brought to room temperature before testing.

Specimen preparation (see illustration):

- (1) Take out the top and add 1 mL (30 drops) of the sample diluent in the stool collection tube.
- (2) Use the stick to pick up a little sample. Close the tube with the diluent and stool sample. (3) Shake the tube in order to assure good sample dispersion.

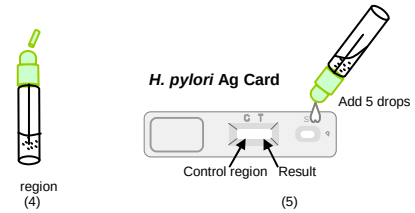


PRECAUTIONS

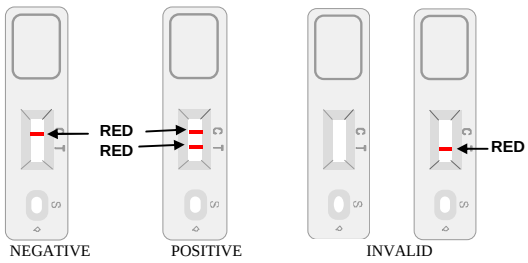
1. The instructions must be followed to obtain accurate results.
2. Appropriate precautions are necessary in the collection, handling of the specimens and used assay materials as potentially biohazardous.
3. Do not use kit beyond the expiration date, which appears on the package label. Do not mix reagents or components from different lots of test kits.
4. For each sample, use one buffer tube and one card. Do not reuse the buffer tube or the card.
5. The tests should be discarded in a proper biohazard container after testing.

ASSAY PROCEDURE

1. Refrigerated specimens and other test materials, including devices, must be equilibrated to room temperature **(15-30º C)** before testing to avoid invalid results.
2. Use a separate stool collection tube and device for each sample or control. Label them with specimen identification.
3. Proceed to shake the stool collection tube in order to assure good sample dispersion.
4. Cut the end of the top (4).
5. Remove the device from its sealed bag just before using. **Do not open pouches until ready to perform the assay.**
6. Dispense exactly 5 drops or 150 µL into the circular window marked with an arrow, avoiding to add solid particles with the liquid (5). In case the tests did not run due to solid particles fallen into the round window, stir the sample added or dispense a drop of extraction buffer until seeing the liquid running through the reaction zone.
7. Read the result at **10 minutes** (the coloured bands appear).



INTERPRETATION OF RESULTS



NEGATIVE: Only one RED band appears across the central window in the site marked with the letter C (control line).

POSITIVE: In addition to the RED control band, another RED band (test line) also appears in the site marked with the letter T (result line).

INVALID: A total absence of the control coloured band regardless the appearance or not of the result line. 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 with a new test. If the problem persists, discontinue using the test kit and contact you local distributor.

Notes

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

- **Built-in Control Features**

This test contains a built-in quality control feature, the red line appearing in the control region (C). It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be clear and not interfere with the ability to read the result.

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- **External Quality Control**

External controls are recommended, positive and negative, to monitor the performance of the assay.

LIMITATIONS

1. This test is a qualitative assay for professional *in vitro* diagnostic use only.
2. The test must be carried out within 2 hours of opening the sealed bag.
3. An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
4. Some stool samples can decrease the intensity of the control red line.
5. 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

Detection limit: A culture of *H. pylori* bacteria was sonicated, centrifuged and its protein concentration was determined. This reference antigen preparation of *H pylori* was diluted in the PBS-BSA buffer and tested in accordance with the kit instructions. The detection limit of *Helicobacter pylori* is **4-8 ng/mL**.

Specificity

The evaluation was conducted comparing the results obtained using the *Helicobacter pylori* Fecal test to another available commercial ELISA assay.
The detection of *Helicobacter pylori* showed 95% of concordance with the commercial ELISA assay.
The antibodies used to elaborate the *Helicobacter pylori* Fecal test 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 *Helicobacter pylori* Fecal test.

Cross Reactivity and Interference

The possibility for interference by human anti-mouse antibodies (HAMA) or high levels of RF in the stools sample, has not been evaluated. Some stool samples could produce control lines with a light red colour.

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).

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