CLONATEST HELICOBACTER PYLORI

Helicobacter Pylori Ag

A rapid test for the qualitative detection of Helicobacter pylori in faeces.

ONE STEP

COD CT42451
20 Test
For *in vitro* diagnostic use only

SUMMARY

The Linear *Helicobacter pylori* Ag 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 control band region, a green coloured band always appears. The presence of this green 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.

PACKAGING CONTENTS

REF CT 42451 20 helicobacter pylori Ag cassettes
20 Stool collection tubes with buffer

STORAGE AND STABILITY

Store at 2-30ºC.
The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

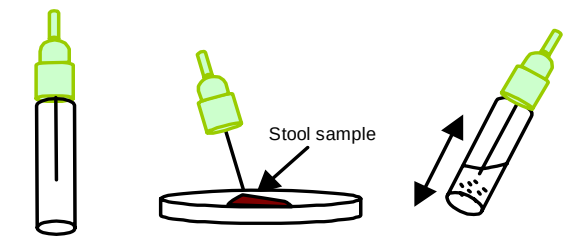
SPECIMEN COLLECTION AND PREPARATION

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 (2-4 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 (see illustration):

(1) Use the stick to pick up a little sample. Close the tube with the diluent and stool sample.

(2) Shake the tube in order to assure good sample dispersion.



Stool Collection Tube (1) (2)

MATERIALS REQUIRED

- Specimen collection container
- Disposable gloves
- Timer.

PROCEDURE

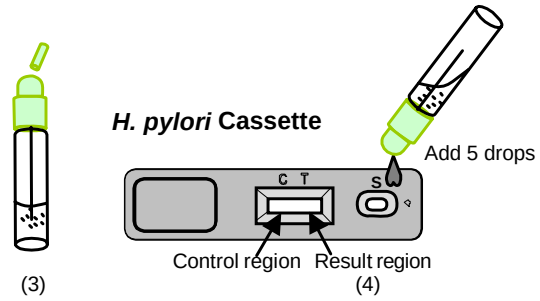
Allow the tests, stool samples and controls to reach to room temperature (15-30ºC) prior to testing. Do not open pouches until ready to perform the assay.

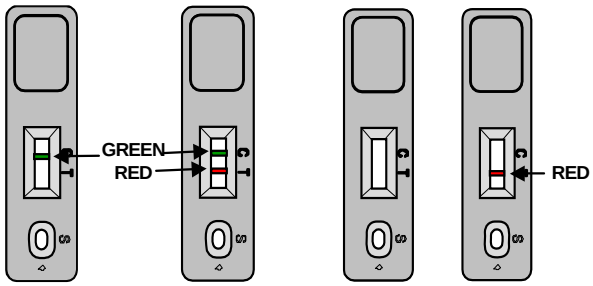
1. Proceed to shake the stool collection tube in order to assure good sample dispersion. Cut the end of the top (3).

2. Remove the *H. pylori* Ag device from its sealed bag just before using.

3. Use a separate stool collection tube and device for each sample or control. Dispense exactly 5 drops or 150 µL into the circular window marked with an arrow, avoiding to add solid particles with the liquid (4).

4.- Read the result at **10 minutes** (the coloured bands appear).





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

***POSITIVE*:** In addition to the GREEN 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.

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ISO 9001 ISO 13485

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QUALITY CONTROL

Internal procedural controls are included in the test. A GREEN line appearing in the control region (C) is the internal procedural control. 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.

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* 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.

ANALYTICAL PERFORMANCE

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* Ag 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 *H. pylori* Ag 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 *H. pylori* Ag.

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

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.

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 tests should be discarded in a proper biohazard container after testing.

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 stool samples can decrease the intensity of the control green line.
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.

REFERENCES

1. Cutler AF. Testing for Helicobacter pylori in clinical practice. Am j. Med. 1996; 100:35S-41S
2. Soll, AH. Pathogenesis of pectic ulcer and implications for theraphy. New England J. Med. (1990), 322: 909-16.
3. Martin J. Blaser. Helicobacter pylori and gastric diseases. BMJ; 316: 1507-1510 (1998).

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