HELICOBACTER PYLORI CARD IN FAECES

Qualitative Determination
of Helicobacter Pylori in Faeces

20 tests **REF 4062**

PRINCIPLE

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 up to 80% of gastric ulcers and more than 90% of duodenal ulcers.
The Helicobacter Pylori card is a qualitative immunochromatographic assay for the determination of H. pylori in the faeces samples.
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 red coloured band always appears.

REAGENTS

Kit components:	REF 4062	Quantity
Cards		**20**
***Collection vials**		**20**
(vials contain 2 ml of extraction solution)		
Labels		**40**

STABILITY: the cards and the diluent are stable until the expiration date when stored at 4-30°C.
Do not freeze. Do not store in fridge.

SAMPLE

Faeces.
Do not use watery and diarrhoeal stool samples.
STABILITY: 2 days at 2°-8°C, up to a year if frozen at -20°C.
In this case, the sample will be totally thawed, and brought to room temperature before using in the test.

SAMPLE PREPARATION

1. Let sample to reach room temperature before using in the test.
2. Collect the stool sample in a clean and dry container. Unscrew the top of sample collection device and collect a small quantity of faeces (about 250 mg) dipping in the sample the tip of the collection stick (about 1 cm).
3. Return the sample collection stick inside the collection device and screw it firmly.
4. Shake the vial to dissolve the sample.
5. Break the tip of the cap and use the vial like a dispenser.

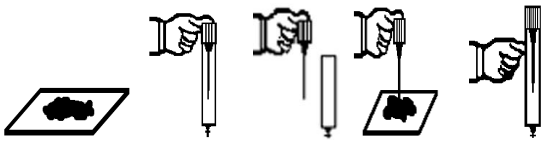


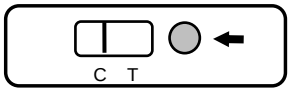
Figure: Collect sample, take sample with the stick and put it inside the vial again.

ASSAY PROCEDURE

1. Remove the card from its bag just before using.
2. Break the tip of the cap of collection vial and pipette exactly **4 drops** (250 µl) into the circular well marked with an arrow **( ),** avoiding to add solid particles with the liquid**.**
   In the case the tests did not run due to the 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.
3. Read the result in **10 minutes**.

INTERPRETATION OF THE RESULTS

NEGATIVE RESULT:

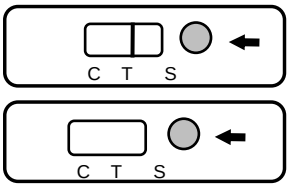


Only **a RED band** appears across the central window in the site marked with the letter C (control line).

POSITIVE RESULT:

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

INCONCLUSIVE RESULT:



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 card. If the problem persists, discontinue using the test kit and contact your local distributor.

PERFORMANCE

Sensitivity: > 99% as regards a commercial available ELISA method.

Specificity: the evaluation was conducted comparing the results obtained using H. Pylori card test to an ELISA assay. The detection of H. Pylori showed a 99% of concordance with the ELISA assay.
The antibodies used to elaborate H. Pylori card recognise epitopes present in the antigen found in stool patients, as well as in preparations from the bacteria cultures in vitro. Sonicated H. Pylori extract from different commercial samples react with H. Pylori card.
The possibility for interference by human anti-mouse antibodies (HAMA) or high levels of RF in the stools sample, has not evaluated.

LIMITATIONS AND NOTES

1. (*) I reagenti contrassegnati con l'asterisco contengono sostanze pericolose. Leggere le Schede di sicurezza.
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 repeated the test.
4. Some stool samples can decrease the intensity of the red line.
5. This test provides a presumptive diagnosis of H. 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.
6. The intensity of the red coloured band in the test result region (T) will vary depending on the concentration of the antigens in the specimen. However, neither the quantitative, nor the rate of increase in antigens can be determined by this qualitative test.
7. Disposal of all waste material should be in accordance with law.

REFERENCES

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3. John L. Telford, Antonello Covacci, Rino Rappuoli Paolo Ghiara. *Immunobiology of Helicobacter pilori infections*. Current Opinion in Immunology, 9; 498-503 (1997).

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