

Helicobacter pylori Antigen Test

IVD For in- vitro diagnostic use only

2°C 8°C
Store at (2-8°C)

INTENDED USE

A rapid one step test for the detection of H.pylori antigen in stool samples.

PRINCIPLE

The Helicobacter pylori antigen reacts with the conjugate-Red latex particles sensibilized with anti-H.pylori monoclonal antibody coated to the membrane of the test. The formed H.pylori-conjugate complex, which migrates upward the membrane by capillarity, binds to the specific antibody molecules fixed to the reaction zone. The excess of complex keeps migrating through the membrane until reaching the C zone of control, where will bind to another specific antibody coated to the membrane forming a green band. The green band presence confirms the functionality of the test.

MATERIALS

MATERIALS PROVIDED

- Test Cassette
- Sample diluent in extraction tubes.
- H.pylori Positive Control.
- Package insert.

MATERIALS NEEDED BUT NOT PROVIDED

- Tubes or vials.
- Disposable gloves.
- Shaker/vortex.
- Timer.

STORAGE AND STABILITY

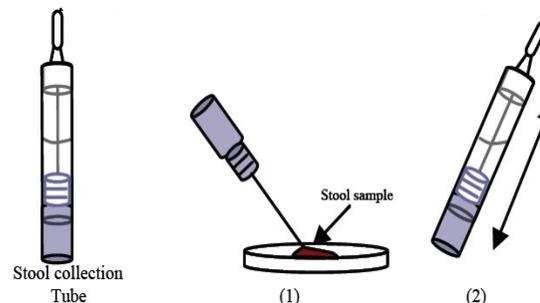
- Store at 2-8°C.
- The reagents are stable until the expiry date stated on the label.

SAMPLES PREPARATION

- Stool: Do not use watery or diarrhoeal samples.
- Collect the stool sample in a clean container and use as soon as possible.
- The samples can be stored at 2-8°C for a longer period of time.

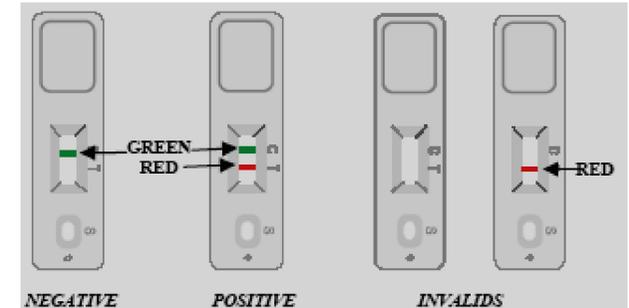
PROCEDURE

- Allow the test device, control and samples to reach room temperature (15-30°C) prior to testing. Do not open the package until ready to perform the assay.
- Using the applicator stick of the provided sample diluent vial, transfer a small portion (5mm diameter) of stool specimen into the sample diluent. (Refer to the illustration below)
- Shake gently in order to unstuck and facilitate the sample dispersion.
- Hold the vial and break the tip off.
- Add 4 drops to the sample well in the test device.
- For positive control: add 75µL of the control to the sample well in the test device.
- Read the result after 5 minutes.



READING THE RESULTS

Look at the colored bands in the test device



Negative: only one GREEN band (Control Line) appears in the white central zone of the reaction strip (Control zone)

Positive: 2 bands appear; in addition to the GREEN control band, a RED band in the zone marked with T (Result Line) also appears.

Invalid: No colored bands appear or only one band appears in the T zone. If an inconclusive result is obtained, re-assay the sample again with a new strip.

QUALITY CONTROL

Internal procedural controls are included in the test. A green band appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

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 cause more than 90% of duodenal ulcers and up to 80% of gastric ulcers.

ANALYTICAL PERFORMANCE

- Sensitivity: The minimum detectable unit of H.Pylori Antigen is of 4-8ng/ml.
- Comparison of methods: the comparison of Helicobacter pylori one step with a commercial ELISA assay shows a concordance level of 95%.
- Specificity: agnostic specificity. The monoclonal antibodies used in the manufacturing of

Helicobacter pylori one step. The antibodies used to elaborate the H.Pylori device + 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 react with H.Pylori device+.

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

LIMITATIONS

- The test must be carried out within 2 hours of opening the dealed bag.
- The clinical diagnosis must not be done with the results of an loy assay, the clinical background of the patient must also be taken in account.

NOTES

- An excess of sample can lead to an inconclusive result, brown colored low defined lines with no diagnostic values may appear. The sample should be diluted again with the diluent and the test should be repeated.
- Some samples may diminish the intensity of the green control band.
- If the assay is inconclusive as a result of solid particles in the reaction zone, take them out and add a drop of diluent, until migration of the reaction mix is observed.
- The intensity of the red colored band in the result line region (T) will vary depending on the concentration of antigens present in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.
- The most common causes of an inconclusive result are: insufficient addition of sample, wrong procedural techniques or deterioration of the reagents. Review the procedure and repeat the tests with a new test. If the problem persists,

discontinue using the test kit and contact to your local distributor.



ATLAS MEDICAL

William James House, Cowley Road,

Cambridge, CB4 0WX, UK.

Tel: +44 (0) 1223 858 910

Fax: +44 (0) 1223 858 524

PPI1017A01

Rev A (13.07.2015)

| | | | |
|--|--|--|---------------------------------------|
|  REF | Product Reference No. |  IVD | For in-vitro diagnostic use. |
|  | Caution. |  | Store at |
|  | Read product insert before use. |  | Number of tests in the pack. |
|  LOT | Lot (batch) number. |  | Manufacturer. |
|  | Expiry date. |  | Manufacturer telephone number. |
|  | Manufacturer fax number. | | |