

## Atlas Helicobacter pylori Antigen Test

A rapid one step test for the detection of  
H.pylori antigen in stool samples.  
**For in vitro diagnostic use only**

Store 2-30°C

### PRINCIPLE

The Helicobacter pylori antigen reacts with the conjugate-Pink Red latex particles sensibilized with anti-H.pylori monoclonal antibody coated to the membrane of the strip. 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 Blue band. The Blue band presence confirms the functionality of the strip.

### REAGENT COMPOSITION

- Helicobacter pylori. Reaction strips coated with anti-H.Pylori monoclonal antibodies conjugated with latex particles and other specific monoclonal antibodies
- Diluent

### Kit CONTENTS

1. Test Strip
2. Sample diluent

### STORAGE AND STABILITY

Store at 2-30°C

The reagents are stable until the expiry date stated on the label.

### SAMPLES

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.

### MATERIALS REQUIRED

- Specimen collection container.
- Tubes or vials.
- Disposable gloves.
- Shaker/vortex.
- Timer.

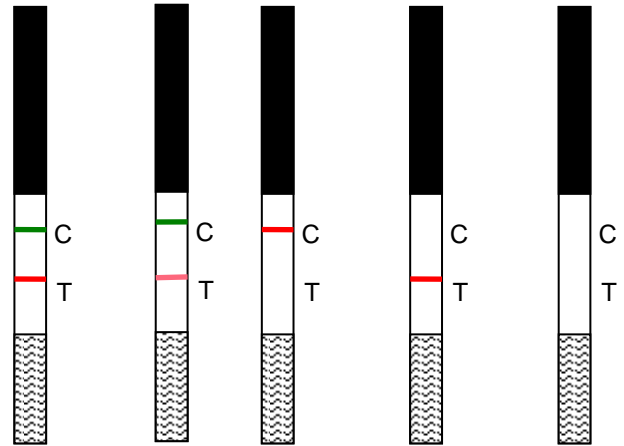
### PROCEDURE

1. Allow the test strips and samples to reach room temperature (15-30°C) prior to testing. Do not open the package until ready to perform the assay.
2. Using the applicator stick of the provided sample diluent vial, transfer a small portion (5mm diameter) of stool specimen into the sample diluent.
3. Shake gently in order to unstuck and facilitate the sample dispersion .

4. Using a pipette, extract some liquid from the topside and dispense in a small tube or vial, enough to get a deepness of 1cm or less.
5. Immerse the test strip in the liquid prepared in step 5. Do not exceed the line shown on the strip.
6. Read the result 5 minutes after the immersion of the strip.

### READING

Look at the colored bands in the strip



Positive

Negative

Invalid

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

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

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 Blue 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: diagnostic 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 Blue color.

#### **LIMITATIONS**

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

#### **NOTES**

1. 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.
2. Some samples may diminish the intensity of the Blue control band.
3. 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.
4. The intensity of the Pink 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.
5. 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 Rd,**  
**Cambridge, CB4 0WX**  
**Tel: ++44 (0) 1223 858 910**  
**Fax: ++44 (0) 1223 858 524**

PPI180A01  
Revision A (20.04.2005)