

H. pylori

One Step

H. pylori Test Device (Serum/Plasma)

A rapid, one step test for the qualitative detection of antibodies to *Helicobacter pylori* (*H. pylori*) in serum or plasma.

For professional *in vitro* diagnostic use only.

INTENDED USE

ATLAS *H. pylori* One Step Test Device (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies to *H. pylori* in serum or plasma to aid in the diagnosis of *H. pylori* infection.

SUMMARY

H. pylori is a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum. It is implicated in the etiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcer, non-ulcer dyspepsia and active and chronic gastritis.^{1,2}

Both invasive and non-invasive methods are used to diagnose *H. pylori* infection in patients with symptoms of gastrointestinal disease. Specimen-dependent and costly invasive diagnostic methods include gastric or duodenal biopsy followed by urease testing (presumptive), culture, and/or histologic staining.³ Non-invasive techniques include the urea breath test, which requires expensive laboratory equipment and moderate radiation exposure, and serological methods.^{4,5}

Individuals infected with *H. pylori* develop serum antibodies which correlate strongly with histologically confirmed *H. pylori* infection.^{6,7} ATLAS One Step *H. pylori* Test Device (Serum/Plasma) is a simple test that utilizes a combination of *H. pylori* antigen coated particles and anti-human IgG to qualitatively and selectively detect *H. pylori* antibodies in serum or plasma in just minutes.

PRINCIPLE

ATLAS *H. pylori* One Step Test Device (Serum/Plasma) is a qualitative membrane strip based immunoassay for the detection of *H. pylori* antibodies in serum or plasma. In this test specimen or specimen followed by buffer is added to the specimen well of the test device. The specimen migrates chromatographically along the length of the test strip contained within the device and interacts with the reagents on the strip. If the specimen contains *H. pylori* antibodies, a colored line will appear in the test

line region indicating a positive result. If the specimen does not contain *H. pylori* antibodies, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test device contains *H. pylori* antigen coated particles and anti-human IgG coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use beyond expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect test results.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- ATLAS *H. pylori* One Step Test Device (Serum/Plasma) can be performed using either serum or plasma.
- Only use sodium heparin or lithium heparin tubes to collect plasma specimens. Do not use EDTA collection tubes.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after specimens collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing.

Specimens should not be frozen and thawed repeatedly.

- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

PROCEDURE

Materials Provided

- Test devices
- Disposable specimen droppers.
- Package insert

Materials Required but not Provided

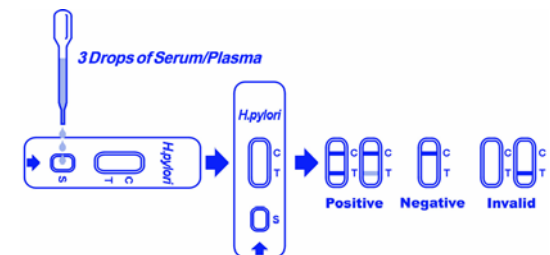
- Specimen collection containers
- Centrifuge
- Timer

Directions for Use

Allow the test device, specimen and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface.
For **Serum or Plasma** specimen: Hold the dropper vertically and transfer 3 drops of serum or plasma (approx. 100µl) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). Please see the illustration below.
3. Wait for the red line(s) to appear. The result should be read at 10 minutes.

Note: Low levels of *H. pylori* antibodies might result in a faint line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE*: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

***NOTE:** The intensity of the red color in the test line region (T) will vary depending on the concentration of *H. Pylori* antibodies present in the specimen. Therefore, any shade of red line in the test region (T) should be considered positive.

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red 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 also required.

Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. *ATLAS H. pylori* One Step Test Device (Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of *H. pylori* antibodies in serum or plasma specimens only. Neither the quantitative value nor the rate of increase in *H. pylori* antibody concentration can be determined by this qualitative test.
2. *ATLAS H. pylori* One Step Test Device (Serum/Plasma) will only indicate the presence of *H. pylori* antibodies in the specimen and should not be used as the sole criteria for the diagnosis of *H. pylori* infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *H. pylori* infection.

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