



H. pylori

One Step

H. pylori Test Device (Whole Blood/Serum/Plasma)

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

For professional *in vitro* diagnostic use only.

INTENDED USE

ATLAS *H. pylori* One Step Test Device (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies to *H. pylori* in whole blood, 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 (Whole Blood/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 whole blood, serum or plasma in just minutes.

PRINCIPLE

ATLAS *H. pylori* One Step Test Device (Whole Blood/Serum/Plasma) is a qualitative membrane strip based immunoassay for the detection of *H. pylori* antibodies in whole blood, 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 (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- Only use sodium heparin or lithium heparin tubes to collect venipuncture whole blood and plasma specimens. Do not use EDTA collection tubes.
- To collect fingerstick Whole Blood Specimens:
 - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
 - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
 - Puncture the skin with a sterile lancet.

Wipe away first sign of blood.

- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add the Fingerstick whole blood specimen to the test device by using a capillary tube:
- Touch the end of the capillary tube to the blood until filled to approximately 50µL. Avoid air bubbles.
- Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well (S) of the test device.
- Add the Fingerstick Whole Blood specimen to the test device by using hanging drop:
 - Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test device.
 - Allow 2 hanging drops of fingerstick whole blood to fall into the specimen well (S) of the test device, or move the patient's finger so that the hanging drop touches the specimen well (S). avoid touching the finger directly to the specimen well (S).
- 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. whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- 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
- Buffer (for whole blood only)
- Package insert

Materials Required but not Provided

- Specimen collection containers
- Lancets (for fingerstick whole blood only).
- Disposable heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)
- 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.
For **Venipuncture Whole Blood** specimen: Hold the dropper vertically and transfer 2 drops of whole blood (approximately 50uL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µl) and start the timer.
For **Fingerstick Whole Blood** specimen:
 - To use a capillary tube: Fill the capillary tube and transfer approximately 50uL of fingerstick whole blood specimen to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µl) and start the timer.
 - To use hanging drop: Allow 2 hanging drop of fingerstick whole blood specimen (approximately 50 µl) to fall into the center of the specimen well (S) on the test device, then add 1 drop of buffer (approximately 40 µl) and start the timer.
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 30 minutes.

INTERPRETATION OF RESULTS

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 (Whole blood/Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of *H. pylori* antibodies in whole blood, 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 (Whole blood/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.

BIBLIOGRAPHY

1. Marshall, BJ, McGeachie, DB, Rogers, PAR and Glancy, RG. Pyloric *Campylobacter* infection and gastroduodenal disease. *Med. J. Australia.* 149: 439-44; 1985.
2. Soll, AH. Pathogenesis of peptic ulcer and implications for therapy. *New England J. Med.* 322:909-16; 1990.
3. Hazell, SL, et al. *Campylobacter pyloridis* and gastritis I: Detection of urease as a marker of bacterial colonization and gastritis. *Amer. J. Gastroenterology.* 82(4):292-96; 1987.
4. Loffeld, RJLF, et al. Usefulness of several commercial enzyme-linked immunoassays for detection of *Helicobacter pylori* infection in clinical medicine. *Euro. J. Gastroen. Hepa.* 5:333-37; 1993.
5. Cutler, AF, et al. Accuracy of invasive and non-invasive tests to diagnose *Helicobacter pylori* infection. *Gastroenterology.* 109: 136-141; 1995.
6. Ansorg, R, Von Recklinghausen, G, Pomarius, R and Schmid, EN. Evaluation of techniques for isolation, subcultivation and preservation of *Helicobacter pylori*. *J. Clin. Micro.* 29:51-53; 1991.
7. Megraud, F, Bassens-Rabbe, MP, Denis, F, Belbouri, A and Hoa, DQ. Seroepidemiology of *Campylobacter pylori* infection in various populations. *J. Clin. Micro.* 27: 1870-3; 1989.

ATLAS Medical

Unit 4, William James House
Cowley Rd, Cambridge, CB4 0WX

Tel: ++44 (0) 1223 858 910

Fax: ++44 (0) 1223 858 524

PPIO70A01

Revision B (12.06.2004)