



Rapid Test for *H. pylori*

A rapid, one step test for the qualitative detection of *H. pylori* in serum or plasma.

For *In Vitro* Diagnostic Use
Not for Sale in U.S.

Intended Use

The American Bionostica One Step H. Pylori Test Device is a rapid chromatographic immunoassay for the qualitative detection of *H. pylori* in serum, plasma or whole blood.

Summary

Helicobacter pylori (*H. pylori*) was initially isolated by Warren and Marshall from biopsy samples taken from patients suffering from active chronic gastritis. *H. pylori* is the principle etiologic agent in type B gastritis (chronic active antral gastritis) for which it appears to be the triggering and perhaps aggravating factor. Increasing data are being accumulated regarding the fundamental role of *H. pylori* in active chronic gastritis, in gastric ulcer and in duodenal ulcer and its close correlation with gastric lesions. *H. pylori* is isolated in culture medium and examined by microscopy after staining or is detected by urease test. Both these techniques are lengthy to conduct and their sensitivity and specificity have yet to be demonstrated. The immunochromatographic technique for the detection of antibodies specific to *H. pylori* has substantially resolved these problems, ensuring rapid serological monitoring using simple, highly specific technology without invasive techniques. The serum test for *H. pylori* can be utilized as a rapid screening process for large populations of patients and highly indicated in the early diagnosis of *H. pylori* infection as the immune response can often precede clinical manifestations of disease. From a diagnostic point of view, a high serum level of specific antibodies against *H. pylori* must be interpreted as an indication of type B asymptomatic gastritis.

Principle of the Test

The *H. pylori* test is a rapid test for the qualitative detection of antibodies of all isotypes (IgG, IgM, IgA, etc) specific to *Helicobacter pylori* in human serum, plasma or whole blood. This test kit is intended as an aid in the diagnosis of *H. pylori* infection in patients with gastrointestinal symptoms. The *H. pylori* test contains a membrane strip, which is pre-coated with *H. pylori* capture antigen on test band region. The *H. pylori* antigen– colloid gold conjugate and serum sample moves along the membrane chromatographically to the test region (T) and forms a visible line as the antigen-antibody-antigen gold particle complex forms with high degree of sensitivity and specificity. This test device has a letter of T as “Test Line” and C as “Control Line” on the surface of the case. Both the Test Line and Control Line in the result window are not visible before applying any samples. The Control Line is used for a procedural control. The Control line should always appear if the test procedure is performed properly and the test reagents of the control line are working.

Materials

Materials Provided:

- Test devices
- Disposable specimen droppers
- Buffer
- Package insert

Materials Required but not provided:

- Specimen collection container
- Centrifuge
- Timer

Stability and Storage Conditions

H. pylori test devices should be stored at room temperature. The test device is sensitive to humidity and as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration.

General Precautions

- For in vitro diagnostic use only.
- Do not eat or smoke while handling specimens.
- Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
- Avoid splashing or aerosol formation.
- Clean up spills thoroughly using an appropriate disinfectant.
- Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
- Do not use the test kit if the pouch is damaged or the seal is broken.

Specimen Collection and Preparation

- The American Bionostica *H. pylori* One Step Test Device (Serum/Plasma/Whole Blood) can be performed using Serum, Plasma or Whole Blood.
- 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 the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. 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.

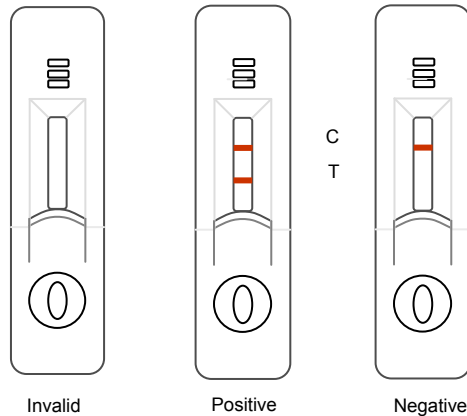
Test Procedure

Allow the test device, Serum, Plasma or Whole Blood) 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. Add 10µl of Serum, Plasma or 20µl of Whole Blood and then 1 drop of chase buffer to the specimen well (S) of the test device, and start the timer. Avoid trapping air bubbles in the specimen well (S).
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 Test Results



- 1) As the test begins to develop, a colored band will appear in the top section of the Result Window to show that the test is working properly. This band is the "Control Line."
- 2) The lower section of the Result Window indicates the test results. If another color band appears in the lower section of the Result Window, this band is the "Test Line."

Negative Result:

The presence of only one purple color band within the result window indicates a negative result.

Positive Result:

The presence of two color bands ("T" band and "C" band) within the result window, no matter which band appears first, indicates a positive result.

Invalid Result:

If the purple color band is not visible within the result window after performing the test, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.

Note: A positive result will not change once it has been established at 10 minutes. However, in order to prevent any incorrect results, the test should not be interpreted after 20 minutes.

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. The American Bionostica *H. pylori* One Step Test Device (Serum/Plasma/Whole Blood) is for *in vitro* diagnostic use only. The test should be used for the detection of *H. pylori* antibodies in Serum, Plasma or Whole Blood specimen only. Neither the quantitative value nor the rate of increase in *H. pylori* antibody concentration can be determined by this qualitative test.
2. The American Bionostica *H. pylori* One Step Test Device (Serum/Plasma/Whole Blood) 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:

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- 4) Evans, D.J., Evans, D.G., Graham, D.Y. and Klein, P.D. A sensitive and specific serologic test for detection of *Campylobacter pylori* infection. *Gastroenterology.* 96: 1004-1008 (1989)