



H. pylori Ab SPW Rapid Test Cassette Frequently Asked Questions (FAQ)

Q: How does the test work?

A: The *H. pylori* Antibody Rapid Test Cassette (Serum/Plasma/Whole Blood) is a qualitative membrane based immunoassay for the detection of *H. pylori* antibodies in whole blood, serum, or plasma. Anti-human IgG is immobilized in the test line region. After specimen is added to the specimen well of the cassette, it reacts with *H. pylori* antigen coated particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized anti-human IgG. 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 in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Q: What can this test help diagnose?

A: This test can help diagnose *H. pylori* infection. The test detects *H. pylori* antibodies, the presence of which indicates a current or previous infection. A positive result indicates the presence of antibodies created in response to an *H. pylori* infection, but further testing will be needed to confirm a current infection.

Q: What is the difference between an antibody test and an antigen test for *H. Pylori*?

A: The antibody test for *H. pylori* is performed on serum, plasma, or whole blood. This test would detect antibodies from a current or previous infection. The *H. pylori* antigen test is performed on feces and would only detect a current infection.

Q: Can fingerstick blood be used for this test?

A: Yes, however whole blood collected by fingerstick should be tested immediately.

Q: Are there any limitations to this test?

A: Neither the quantitative value nor the rate of increase in *H. pylori* antibodies can be determined by this qualitative test.

- The *H. pylori* Antibody Rapid Test Cassette 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
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- 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.

Q: How accurate is the test?

A: The *H. pylori* Rapid Test Cassette has been evaluated in a clinical study in which it was compared with a leading ELISA *H. pylori* test, demonstrating an overall accuracy of 97.2%. It features a relative sensitivity of 94.7% and relative specificity of 99.4%.

Q: How do I know that the test was run properly?

A: A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.



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