H. pylori Ab SP Rapid Test Cassette

Frequently Asked Questions (FAQ)

Q: How does the test work?

A: The *H. pylori* Antibody Rapid Test Cassette (Serum/Plasma) is a qualitative membrane based immunoassay for the detection of *H. pylori* antibodies in 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* s performed on serum or plasma. 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: 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.

aconlabs.com

ACON Laboratories, Inc.
10125 Mesa Rim Road, San Diego, CA 92121, U.S.A.
Tel: 1.858.875.8000
Fax: 1.858.200.0729
Email: info@aconlabs.com

PN 2190016201 • Date 5/19