Sirin Diagnostics H. Pylori Ab Test Cassette (WB/Serum/Plasma)

For In Vitro Diagnostic and Professional Use Only

INTENDED USE

The H. Pylori Test Ab Cassette is a chromatographic immunoassay (CIA) for the rapid determination of antibodies of H. Pylori in whole blood, serum or plasma specimens. The test is used as an aid in the diagnosis of the infection due to H. Pylori.

SUMMARY

The infection of Helicobacter pylori (H. Pylori) is associated with a variety of gastrointestinal diseases, such as stomach ulcers, chronic active gastritis and gastrointestinal adenocarcinoma. Antibodies of H. Pylori developed in individuals infected with H. Pylori as a serological response. Detecting specific antibodies of H. Pylori can be used as a qualitative assay in the diagnosis of H. Pylori infection, either as an adjunct to endoscopy or as an alternative measure in symptomatic patients.

PRINCIPLE

H. Pylori Test Ab Cassette is a lateral flow, immunochromatographic screening test. H. Pylori specific antigens are pre-coated onto membrane as a capture reagent in the test region. During the assay, the specimen is first allowed to react with H.Pylori specific antigen-gold conjugate complexes. The mixture then moves laterally on the membrane to the test region which is coated with immobilized antigen of H. Pylori. If H. Pylori antibodies are present in the specimen, a colored line will form in the test (T) region. Absence of the colored line in the test region indicates a negative result. To serve as a procedural control, a colored line in the control (C) region will appear demonstrating that the test has been performed correctly and the reagents of the test are working.

PRECAUTIONS

1. Read instruction for use carefully before performing this test.
2. For in vitro diagnostic use only.
3. Do not use the test Cassette beyond the expiration date.
4. The test Cassette should remain in the sealed pouch until use. Do not use the test cassette if the pouch is damaged or the seal is broken.
5. Do not reuse Cassette.
6. Treat and properly handle the specimens and used cassette as if they were potentially infectious.

STORAGE AND STABILITY

The test Cassette should be stored at 2-30C in the sealed pouch. Avoid humidity, heat and direct sunlight. The test Cassette is stable through the expiration date printed on the sealed pouch. DO NOT FREEZE.

WARNINGS

1. There should be no eating, drinking or smoking where specimens are being handled.
2. Wear disposable gloves and a lab coat while handling specimens. Wash hands thoroughly afterwards.
3. Avoid splashing or aerosol formation.
4. Clean spills thoroughly using an appropriate disinfectant.

SPECIMEN COLLECTION AND STORAGE

Whole Blood Specimen

1. Clean the area to be lanced with alcohol pad.
2. Squeeze the fingertip and pierce it with sterile gauze of cotton.
3. Using a disposable pipette, collect blood from the puncture site.
4. Using a disposable pipette, collect blood from the puncture site.

The whole blood may be used for testing immediately or may be refrigerated at 2-8°C up to three days. Specimens that have been refrigerated must be brought and equilibrated to room temperature prior to testing.

Serum or Plasma Specimen

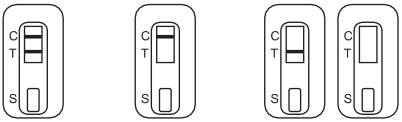
1. Centrifuge whole blood to get plasma or serum specimen.
2. If serum or plasma is not tested immediately, it should be refrigerated at 2-8°C. for storage period greater than three days, freeing is recommended. Such specimen should be brought and equilibrated to room temperature (15-30°C) prior to use.

TEST PROCEDURE

1. Bring the pouched test kit to room temperature (15-30°C) prior to testing. Do not open the pouch until ready to begin testing.
2. Remove the kit from the sealed pouch. Lay it on a flat, clean, and dry surface.
3. Using the provided pipette, add one drop of fresh specimen to the sample well.
4. Hold the buffer bottle vertically and add 1 drop to the sample well. If using a pipette,

change a new one to avoid cross-contamination. Draw and transfer 2-3 drops of buffer to the sample well.
5. Read the result between 15-20 minutes. Do not read the results after 20 minutes.

INTERPRETATION OF RESULTS



Positive Negative Invalid

Positive: Two pink lines appear in the result window, one in the control region and another one in the test region. This indicates a positive result and H. Pylori antibody having been detected.
Negative: Only one pink line appears in the control region(C). This indicates a negative result and H. Pylori antibody having not been detected.
Invalid: If the control line fails to appear, the test result is invalid regardless of the presence or absence of the test line.
NOTE: 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 cassette. If the problem persists, please contact your local distributor.

PERFORMANCE CHARACTERISTICS

1. Sensitivity and Specificity
A clinical study using a total of 150 serum specimens was conducted at various sites. The results of the H. Pylori Ab Test Cassette were compared with a commercially available ELISA test. The sensitivity and specificity of the H. Pylori Ab test results are as given below:

Reference		H.Pylori Ab Test Cassette		Total Result
Method	Result	Positive	Negative	
Commercial ELISA	Positive	57	2	59
	Negative	0	91	91
Total Results		57	93	150

2. Accuracy:
Of 98.7% (148/150) based on internal Quality Control Standards.

LIMITATIONS OF THE TEST

1. The result should be used only as an aid in diagnosis and should not be interpreted as a final diagnosis. To confirm diagnoses of gastritis and or peptic ulcers, clinical findings should be considered.
2. Specimen from patients infected with C. Jejune may have low cross-reactivity with this test.

INDEX OF SYMBOLS

	Consult Instructions for use		Do not re-use
IVD	In vitro diagnostic medical device		Use-by date
	Store at 2-30 °C	LOT	Batch code

MANUFACTURER CONTACT INFORMATION

Sirin Diagnostics
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