Sirin Diagnostics H. Pylori Ag Test Cassette

For In Vitro Diagnostic and Professional Use Only

INTENDED USE

The H.Pylori Ag Test is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of Helicobacter Pylori antigen in feces.

SUMMARY

Helicobater pylori is gram negative bacteria that infects gastric mucosa. Infection with Helicobacter pylori is associated with a variety of gastrointestinal diseases, such as stomach ulcers, chronic active gastritis and gastrointestinal adenocarcinoma. Infection with H.pylori is very common and some techniques, both invasive and non-invasive, have been utilized to diagnose H. pylori infection. The basis for diagnosing H.pylori infection by H.Pylori Ag Test Device is detecting Helicobacter Pylori antigens present in the fecal specimen.

PRINCIPLE

The H.Pylori Ag Test is a lateral flow chromatographic immunoassay based on the principle of the double antibody–sandwich technique. The test cassette consists of: 1) a purple-colored conjugate pad containing H. Pylori antibody conjugated with colloidal gold (H. Pylori conjugates) 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with non-conjugated H. Pylori antibody, and the C line is pre-coated with goat anti-mouse IgG.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. The antigen of H. Pylori if present in the specimen will bind to the H. Pylori conjugates. The immunocomplex is then captured on the membrane by the pre-coated H. Pylori antibody, forming a pink-colored T line, indicating a H. Pylori Ag positive test result.

To serve as a procedural control, a colored line will always appear in the control region indicating that proper volume of specimen has been added and membrane wicking has occurred. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

1. H. Pylori Ag Test: Each device contains a strip with colored conjugates and reactive reagents pre-coated in the corresponding regions.
2. Fecal specimen collection tube.
3. The collection tube contains 1.5 ml of buffer, pH 7.6.
4. Instruction for use

PRECAUTIONS

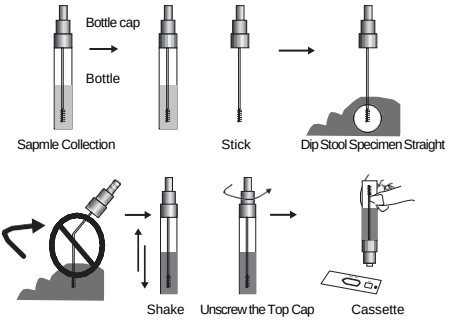
1. Read instruction for use carefully before performing this test.
2. For in vitro diagnostic use only.
3. Do not use the test device beyond the expiration date.
4. The test device should remain in the sealed pouch until use. Do not use the test device if the pouch is damaged or the seal is broken.
5.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

STORAGE AND STABILITY

The test device should be stored at 2-30℃ in the sealed pouch. Avoid humidity, heat and direct sunlight. The test device 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 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

1. Collect stool specimen using the sample collection tube provided.
2. Unscrew the top of the sample collection tube,

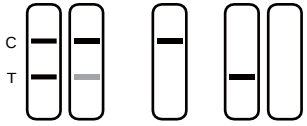
take out the sample collection stick, and collect the specimen by dipping the stick into 3 different places of the feces.

3. Replace the sample collection stick in the tube and screw tightly.
4. If the specimen cannot be tested on the day of collection, store the feces specimen at 4°C. Bring the specimen to room temperature before testing.

TEST PROCEDURE

1. Bring the pouched test device to room temperature (15-30℃) prior to testing. Do not open the pouch until ready to perform the assay.
2. Remove the test device from the sealed pouch. Lay it on a flat, clean and dry surface.
3. Specimen collection. Please see "SPECIMEN COLLECTION AND STORAGE".
4. Shake the sample collection tube well.
5. Holding the sample collection tube upright, carefully twist off the tip of collection tube.
6. Squeeze 2 drops of the specimen solution in the sample well.
7. Read results between 15-20 minutes. Do not read the result after 20 minutes.

INTERPRETATION OF RESULTS



Positive Negative Invalid

Positive: Two distinct pink-colored lines appear, one in the test region (T) and another one in the control region(C). This indicates a positive test result and Helicobacter Pylori antigens having been detected.

Negative: Only one pink-colored line appears in the control region(C). This indicates a negative test results and no Helicobacter Pylori antigens having 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.

QUALITY CONTROL

1. Internal procedural controls are included in the test. A colored line appearing in the control region (C) is considered as an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
2. External controls are not supplied with this kit. 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.

PERFORMANCE CHARACTERISTICS

Table: H. pylori Ag Test Device vs. Endoscopy

Reference		H. pylori Ag Test Device		Total Results
Method	Results	Positive	Negative	
Endoscopy	Positive	130	2	132
	Negative	3	151	154
Total Results		133	153	286

Relative Sensitivity: 98.5% (94.6%-99.8%)
Relative Specificity: 98.1% (94.2%-99.6%)
Overall Agreement: 98.3% (96.0%-99.4%)
95% Confidence Interval

LIMITATION OF THE TEST

1. The H.Pylori Ag Test Device is for professional and in vitro diagnostic use and should only be used for the qualitative detection of Helicobacter Pylori.
2. Following certain antibiotic treatments, the concentration of H. Pylori antigen may decrease to concentrations below the minimum detection level of the test. Therefore, diagnosis should be made with caution during antibiotic treatment.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

INDEX OF SYMBOLS

	Do not re-use		Use-by date
IVD	In vitro diagnostic medical device		Consult instructions for use
	Store at 2-30	LOT	Batch code
	Contains sufficient for <n>tests		

MANUFACTURER CONTACT INFORMATION

Sirin Diagnostics
20/21 3rd Industrial Sector – 2nd Cell -El-Matahra Industrial City – Minia - Egypt

EC REP **CMC Medical Devices & Drugs S.L**
C/Horacio Lengo , 18.29006
Malaga, Spain