Helicobacter Pylori (HP) Antigen Test

Instructions For Use

Format: Cassette
Specimen: Fecal Extract or Biopsy Sample
Catalog Number: A02-11-422

CE

* Please read the instructions carefully before use

INTENDED USE

Artron One-Step *Helicobacter pylori* (HP) Antigen Test is a rapid and convenient immuno-chromatographic assay used for the qualitative detection of *Helicobacter pylori (H.Pylori)* antigen in human fecal samples or a biopsy of a mucosa sample from the stomach lining. It is intended for professional use to aid in the diagnosis of *H. pylori* infection in patients with gastrointestinal symptoms. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.

SUMMARY AND PRINCIPLE OF THE ASSAY

H. pylori is a small, spiral-shaped gram negative bacterium that lives in the surface of the stomach and duodenum. It is implicated in the etiology of a variety of gastrointestinal diseases, including peptic ulcers, gastritis, duodenitis, extra digestive diseases and in some cases, cancer. Over 80 percent of individuals infected with the bacterium are asymptomatic and it has been postulated that it may play an important role in the natural stomach ecology. Individuals infected with *H. pylori* have a 10 to 20% lifetime risk of developing peptic ulcers and a 1 to 2% risk of acquiring stomach cancer. Inflammation of the pyloric antrum is more likely to lead to duodenal ulcers, while inflammation of the corpus (body of the stomach) is more likely to lead to gastric ulcers and gastric carcinoma. However, it is possible that *H. pylori* play a role only in the first stage that leads to common chronic inflammation, but not in further stages leading to carcinogenesis. The continued presence of *H. pylori* is a risk factor for gastric cancer.

Artron One-Step HP Antigen test is an antigen-capture immunochromatographic assay, detecting presence of *H. pylori* antigen in fecal samples. Monoclonal antibodies specifically against *H. pylori* antigen are 1) conjugated with colloidal gold and deposited on the conjugate pad, and 2) immobilized on the Test Zone on the nitrocellulose membrane. When a fecal sample is added, the gold-antibody conjugate is rehydrated and the *H. pylori* antigen, if any in the sample, will interact with the gold conjugated antibodies. The antigen-antibody-gold complex will migrate towards the test window until the Test Zone (T) where they will be captured by immobilized antibodies, forming a visible pink line (Test band) indicative of positive results. If *Helicobacter pylori* antigen are absent in the sample, no pink line will appear in the Test Zone (T).

To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a pink control line in the Control Zone (C) is an indication of an invalid result.

PACKAGE CONTENTS

- Pouch contents: Test Cassette, Desiccant.
- Specimen Collection tube with sample buffer (2 ml/ tube).
- Test instruction.

OTHER MATERIALS REQUIRED (BUT NOT PROVIDED)

- Glove.
- Clock or timer.

WARNINGS AND PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not reuse.
- Do not use if the pouch seal or its packaging is compromised.
- Do not use after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials and performing the assay.
- Wash hands thoroughly after finishing the tests.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Clean up spills thoroughly with appropriate disinfectants.

- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
- Keep out of children's reach.

SPECIMEN COLLECTION AND STORAGE

- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 72 hours.
- Bring specimens to room temperature prior to testing.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

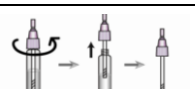
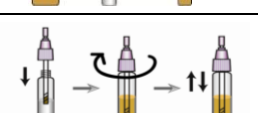
TEST PROCEDURES

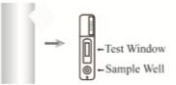
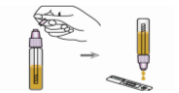
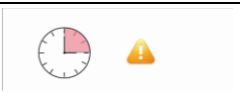
1) For biopsy samples:

- Collect biopsy of mucosa samples from the stomach lining;
- Unscrew the cap of the specimen collection tube and take out specimen collection stick;
- Put the biopsy sample to the specimen collection tube;
- Insert the specimen collection stick into the tube and tighten the cap. Shake the tube vigorously to ensure thorough mixture of the specimen and the assay diluents reagent.
- Follow steps E – G in table below.

2) For fecal samples:

Follow the procedures described below:

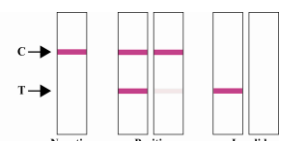
A) Use clean, dry containers for specimen collection. Best results will be obtained if the assay is performed within 6 hours after collection.	
B) Unscrew the cap of the specimen collection tube and take out specimen collection stick.	
For solid specimen: **C-1)** Stab the specimen collection stick into the fecal specimen in at least 3 different sites of the feces to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.	
For liquid specimens: **C-2)** Hold the pipette vertically, aspirate fecal specimens, and then transfer 6 drops (approximately 300 µl) into the specimen collection tube containing the extraction buffer.	
D) Insert the specimen collection stick into the tube and tighten the cap. Shake the tube vigorously to ensure thorough mixture of the specimen and the assay diluents reagent.	

E) Remove the test cassette from the sealed pouch and use it as soon as possible. Caution: Do not touch the test window and the membrane inside	
F) **For Biopsy and Fecal samples prepared above:** Hold the specimen collection tube upright and break off the tip with hands. Invert the vial and add four full drops (150 µl) of specimen without air bubbles into the sample well of the cassette.	
G) Read the results within 15 minutes. Note: Strong positive specimens may produce positive results in as little as 1 minute. Confirm negatives in 15-30 minutes. DO NOT INTERPRET RESULTS AFTER 30 MINUTES	

Note:

- *Best results will be obtained if the assay is performed right after collecting fecal samples.*
- *Specimens prepared in the specimen collection tube may be stored for 6 months at -20°C if not tested within 1 hour after preparation.*

RESULT INTERPRETATIONS



Negative
A pink colored band appears only at the control region (C), indicating a negative result.

Positive
A clear pink control band (C) and a detectable test band (T) appears, indicating a positive result.

Invalid
No visible band at the control region (C). Repeat with a new test device. If test still fails, please contact the distributor with the lot number.

QUALITY CONTROL

Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

STORAGE AND STABILITY

- Test device in the sealed pouch should be stored at 2-30ºC. Do not freeze the test device.
- The Fecal Specimen Collection Device containing the buffer should be stored at 2-30ºC.
- The test device should be kept away from direct sunlight, moisture and heat.

LIMITATIONS

- This product is an *in vitro* diagnostic test designed for professional use only.
- Humidity and temperature can adversely affect results.
- The instructions for the use of the test should be followed during testing procedures.

- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- Although the test demonstrates superior accuracy in detecting *Helicobacter pylori* antigen in fecal extract, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. 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.

MANUFACTURER CONTACT INFORMATION

Artron Laboratories Inc.
3938 North Fraser Way
Burnaby, BC
V5J 5H6 Canada

Ph: 604.415.9757
Fax: 604.415.9795
www.artronlab.com
info@artronlab.com

Wellkang Ltd
Suite B
29 Harley Street LONDON,
W1G 9QR
United Kingdom

Doc No. A02-11-422 **REVISION: October, 2013**