Helicobacter pylori Antigen Test

Instructions For Use

Format: Cassette

For:

Catalog Number: VEL-001-HP(s)

Specimen: Fecal Specimen

* Please read the instructions carefully before use
**INTENDED USE**

Helicobacter pylori Antigen Rapid Test provides a rapid, convenient and easy-to-interpret qualitative immunochromatographic in vitro diagnostic assay for the detection of the presence of Helicobacter pylori antigen in human fecal specimen. This test only provides a preliminary analytical test result; final diagnosis of H. pylori infection should be done in conjunction with other diagnostic methods such as ELISA and PCR.

**SUMMARY AND PRINCIPLE OF THE ASSAY**

*Helicobacter pylori* (H. pylori or HP), previously known as Campylobacter pylori, is a spiral shaped bacterium in the stomach. First identified by Barry Marshall and Robin Warren in 1982, its presence was detected in patients who suffered from chronic gastritis and gastric ulcers, conditions that were not previously believed to be caused by microbes. Infection with H. pylori could also develop duodenal ulcers and stomach cancer. In fact, over 80 percent of H. pylori-infected population is asymptomatic and it has been postulated that it may play a significant role in the natural stomach ecology.

The *Helicobacter pylori* Antigen Rapid Test is an immunochromatographic assay. During the test, the specimen will migrate towards the test window by capillary action, carrying the colored anti-HP antibody-colloid gold conjugate from the pad. In the presence of HP antigen in the specimen, it will form a complex with the colored antibody during migration. This complex will then be captured by another anti-HP antibody immobilized at the test band region, which will reveal a red color. If HP antigen is missing in the specimen, the immobilized antibody would not be able to indirectly capture the colored antibody, no red color will reveal at the test band region. Thus the presence of a red line at the test region indicates a positive result, while the absence of it indicates a negative result.

A control line is included to serve as an internal process control. This control line should be visible in a properly performed test. Absence of a red control line is an indication of an invalid result.

**PACKAGE CONTENTS**

- 25 individually pouched test kits
- Pouch contents: 1 test cassette and 2 desiccants
- 1 bottle of HP Ag Buffer with collection tip
- 1 User Guidebook

**MATERIALS REQUIRED (BUT NOT PROVIDED)**

- Protective gloves
- Surgical mask
- Clock or timer

**WARNINGS AND PRECAUTIONS**

- For in vitro diagnostic use only.
- Do not use after the expiration date. Do not reuse.
- Device should remain sealed in pouch until use.
- Keep out of children’s reach.
- The test cassette should be discarded in a proper biohazard container after testing.

**SPECIMEN PREPARATION**

- Collect fecal samples in a sterile container which do not contain any media, preservatives, additives or any other chemicals.
Specimen mixed with the buffer may be stored up to 1 week at 2 to 8 °C before tested.

Tests work best with freshly prepared samples. If the tests cannot be performed immediately, the fecal samples can be stored at 0 to 8 °C for up to 72 hours. For longer storage period, please keep samples at below -18 °C.

**TEST PROCEDURES**

1. Unscrew the cap of the collection tube.

2. Insert the stick into stool and use only enough fecal material to cover the tip of the applicator stick (approx. 10 – 50 µg). Screw the stick into the tube and secure tightly.

3. Shake the tube well to mix the specimen and the buffer. The specimen is now ready for testing, transportation or storage.

4. Open the pouch and take out the test cassette and place it on a dry, clean and level surface. Transfer 2 to 3 drops into the sample well of the test cassette. Wait at least 5 minutes before reading results. Note: *Do not read results after 15 min.*

**Cautions**

- It is highly recommended to wear protective gloves and surgical mask while handling the specimen.
- Please DO NOT transfer any test sample directly into the test area.
RESULT INTERPRETATIONS

**POSITIVE:** Two distinct red or pink lines appear: one line in the control region (C) and the other in the test region (T).

**NEGATIVE:** One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

**INVALID:** Control line fails to appear. Repeat with a new test device. If test still fails, please contact your local distributor.

**QUALITY CONTROL**
Internal procedural controls are included in the test. A red line will always appear in the control region (C) regardless of positive or negative results. The appearance of the C line indicates that the test has been performed correctly. It confirms sufficient specimen volume and correct procedure technique.

**STORAGE AND STABILITY**
- Store as packaged in the sealed pouch at 2°C~30°C (36°F~86 °F). It is stable until the expiration date printed on the pouch label. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

**LIMITATIONS**
- This device is designed to be tested with human fecal specimen only; testing with other body fluids has not been validated and may yield untrue results.
- False results may be generated beyond the manufacturer's control by inappropriate operations. Please make sure the test is performed by closely following the instructions.
- Single rapid test provides only a preliminary analytical test result; final diagnosis of H. pylori infection should be done in conjunction with other diagnostic methods such as ELISA and PCR.
MANUFACTURER CONTACT INFORMATION

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