

H pylori Antigen Rapid Test Kit

INTENDED USE

The H.pylori Antigen Rapid Test is a lateral flow immunoassay designed to qualitatively detect the H.pylori antigen in human faeces.

INTRODUCTION

H.pylori is linked with various gastrointestinal diseases, such as non-ulcer dyspepsia, duodenal and gastric ulcers, and active, chronic gastritis. When gastrointestinal disease symptoms and signs are present in a patient, the likelihood of an H. pylori infection may surpass 90%. Recent research has suggested that stomach cancer and H. pylori infection are related. When H. pylori colonises the gastrointestinal tract, it produces particular antibody responses that help diagnose H. pylori infection and track the effectiveness of treatment for disorders linked to H. pylori. Additional evidence that the successful removal of H. pylori is linked to clinical improvement in people suffering from gastrointestinal disorders.

PRINCIPLE

The H.pylori Antigen Rapid Test kit is a lateral flow immunoassay for the qualitative detection of H.pylori antigen in human faeces. During this process, Anti-H. Pylori antibody is immobilised in the kit's test line region. When an adequate amount of test specimen is placed in the specimen well, the test specimen reacts with

anti-H. pylori antibody-coated particles that have been placed on the specimen pad. This mixture interacts with the immobilised anti-H. pylori antibody as it migrates chromatographically along the test strip. A colored line indicating a positive result will appear in the test line region if the samples contain H. pylori antigen. A colored line indicating a negative result will not appear in the specified region if the specimen does not contain H. pylori antigen.

MATERIALS AND METHODS

1. Individual sealed pouches, each containing:
 - a. 1 × Test Card
 - b. 1 × Desiccant Pouch
 - c. 1 × Dropper
2. Buffer Tube

STORAGE AND STABILITY

- Keep the test kit between 2 - 30°C in a dry, cool place. Avoid freezing.
- The kit is stable within the expiry date printed on the product label and outer packaging. Do not use later than the specified date.
- The package should be sealed until it is required for use.

SPECIMEN COLLECTION

The H.pylori Antigen Rapid Test Kit can be used on human faeces.

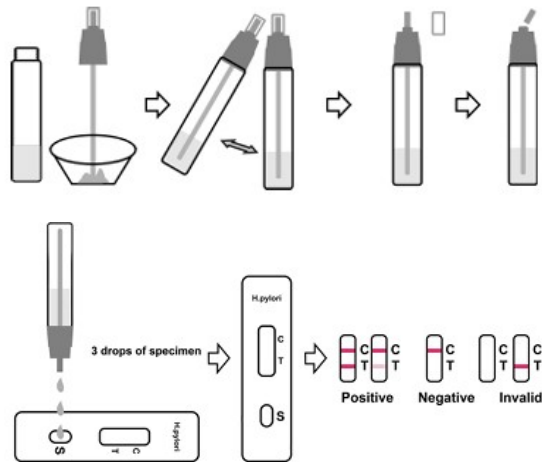
- Collect adequate faeces (1-2 mL or 1-2 g) in a sterile, dry specimen collecting container to obtain maximum antigen as possible (if any). For the best results, the assays should be performed within six hours after collection.
- If the specimen is not examined within six hours, it can be kept for three days at 2–8°C. The specimens should be stored at or below -20°C for long-term storage.
- To collect the specimen, unscrew the cap of the specimen collection tube and jab the specimen collecting applicator into the faecal specimen at least five times to collect around 50 mg of faeces.
- Screw on and tighten the specimen collection tube's cap, then shake to mix the specimen into the dilution buffer. Allow the tube to rest for two minutes.
- Before testing, bring the specimens to room temperature. Frozen specimens need to be thoroughly thawed and mixed. It is not recommended to repeatedly freeze and thaw specimens.

TEST PROCEDURE

1. Allow the test kits and specimens to equilibrate to room temperature (15- 30°C).
2. Bring the pouch to room temperature, and after removing the kit from the pouch, use it as soon as possible.
3. Ensure the test kit is situated on a clean surface, and while holding the specimen collection tube upright, remove the tip with caution. Then, add 3 drops (approximately

100 µL) to the specimen well (S) of the test kit and set the timer.

4. Wait until the colored lines appear. Examine the results after fifteen minutes. The results should not be interpreted after 20 minutes. The test is positive if a colored line appears in the top section (C) and lower section (T) of the result window.



RESULT:

1. Two Pink Lines - (POSITIVE)
2. One Pink Line at (C) - (NEGATIVE)
3. No Pink Line - (INVALID)

LIMITATIONS

1. The H. pylori Antigen Rapid Test Kit is designed for in vitro diagnostic use only. It specifically detects the presence of the H. pylori antigen in human faeces.
2. Please note that this is a qualitative test, meaning it cannot measure the amount of the antigen or track changes over time.

3. As with any diagnostic tool, the results should be interpreted by a physician in conjunction with other clinical findings.
4. If the test results are negative but symptoms persist, further testing using different methods is recommended.

REFERENCES

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