

H. PYLORI ANTIGENS RAPID TEST DEVICE (FECES) For *in vitro* diagnostic Use only

Catalog No. ABT-IDT-B76
Storage 2 - 30°C
Sample Human Fecal Specimens
Results Within 5 minutes

INTENDED USE

The *H. pylori* Antigen Rapid Test Device (Feces) is a rapid visual immunoassay for the qualitative presumptive detection of *Helicobacter pylori* antigens in human fecal specimens. This kit is intended to be used as an aid in the diagnosis of *H. pylori* infection.

INTRODUCTION

Helicobacter pylori (also known as *Campylobacter pylori*) is a spiral-shaped with a typical flagellum, Gram negative bacteria, infecting gastric mucosa. It causes several gastro-enteric diseases such as non-ulcerous dyspepsia, gastric and duodenal ulcer, active gastritis and can even increase the risk of stomach adenocarcinoma, so as to be classified as carcinogen agent type I.

Many *H. pylori* strains have been isolated: among them, the strain expressing CagA antigen is strongly immunogenic and, according to this, it is of utmost clinical importance because it is associated to the cytotoxic factor. It is widely reported in many literature articles that, in infected patients showing antibodies against CagA gene product, the risk of gastric cancer is up to five times higher than the reference group infected with a CagA negative bacterial strain.

The presence of the gene itself determines the persistence of the infection, the ulceration and the protein associated, VacA toxin is frequently the main cause of infiltrations in the gastric mucosa.

This antigen associated to others, such as CagII, CagC, seems to act as starting agent of a sudden inflammatory response which can provoke ulceration (peptic ulcer), allergic episodes, and a decrease of the therapy efficacy.

At present several invasive and non-invasive approaches are available to detect this infection state. Invasive methodologies requires endoscopy of the gastric mucosa with a histologic, cultural and urease investigation, which are cost-effective and requiring long times to come to a correct final diagnosis.

Alternatively, non-invasive methods are available such as Breath Test, which is extremely complicated and not highly selective, or classical ELISA and immunoblotting assays.

PRINCIPLE

The *H. pylori* Antigen Rapid Test Device (Feces) has been designed to detect *Helicobacter pylori* through visual interpretation of color development in the internal strip. The membrane was immobilized with anti-*H. pylori* monoclonal antibody on the test region. During the test, the specimen is allowed to react with colored anti-*H. pylori* monoclonal antibody colloidal gold conjugates, which were precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary action, and interact with reagents on the membrane. If there were enough *H. pylori* antigens in specimens, a colored band will form at the test region of the membrane. Presence of this colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials Provided

• Individually packed test devices • Specimens dilution tube with buffer
• Package insert

Materials Required but Not provided

• Centrifuge • Timer
• Specimens collection container

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- **The *H. pylori* Antigen Rapid Test Device (Feces)** is intended for use with human fecal specimens.
- Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolong periods. Specimens may be stored at 2-8°C for up to 72 hours.
- Bring specimens to room temperature prior to testing.
- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.

PROCEDURE

Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.

1. Specimen collection and pre-treatment:
 - 1) Best results will be obtained if the assay is performed within 6 hours after collection.
 - 2) Unscrew and remove the dilution tube applicator. Be careful not to spill or spatter solution from the tube. Collect specimens by inserting the applicator stick into at least 3 different sites of the feces to collect approximately 50 mg of feces (equivalent to 1/4 of a pea).
 - 3) Place the applicator back into the tube and screw the cap tightly. Be careful not to break the tip of the dilution tube.
 - 4) Shake the specimen collection tube vigorously to mix the specimen and the extraction buffer.
2. Testing
 - 1) Remove the test from its sealed pouch, and place it on a clean, level surface. Label the test with patient or control identification. To obtain a best result, the assay should be performed within one hour.
 - 2) Using a piece of tissue paper, break the tip of the dilution tube. Hold the tube vertically and dispense 2 drops of solution into the specimen well (S) of the test device.



Avoid trapping air bubbles in the specimen well (S), and do not drop any solution in observation window.

As the test begins to work, you will see color move across the membrane.

- 3. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

Note: If the specimen does not migrate (presence of particles), centrifuge the extracted specimens contained in the extraction buffer vial. Collect 80 µL of supernatant, dispense into the specimen well (S) of a new test device and start afresh following the instructions mentioned above.

INTERPRETATION

C T POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

C T NEGATIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T)

C T C T INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

- 1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
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.

LIMITATIONS OF THE TEST

- 1. The H. pylori Antigen Rapid Test Device (Feces) is for professional in vitro diagnostic use, and should be used for the qualitative detection of Helicobacter pylori only.
2. Following certain antibiotic treatments, the concentration of H. pylori antigens may decrease to the concentration 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.

PERFORMANCE CHARACTERISTICS

Table: H. pylori Antigen Rapid Test vs. Endoscope-based methods

Table with 3 columns: Biopsy/Histology/RUT, H. pylori Antibody Rapid Test (+/-), and Total. Includes performance metrics: Relative Sensitivity >99.9%, Relative Specificity >99.9%, Overall Agreement >99.9%, and 95% Confidence Interval.

Specificity:

Cross reactivity with following organism has been studied at 1.0 x 109 organisms/ml. The following organisms were found negative when tested with the One Step H.pylori Antigen Test Device (Feces).

- Staphylococcus aureus Proteus mirabilis Neisseria gonorrhoea

Table listing various bacteria and their detection by the test: Pseudomonas aeruginosa, Acinetobacter spp, Group B Streptococcus, Enterococcus faecalis, Salmonella choleraesius, Proteus vulgaris, Group C Streptococcus, Gardnerella vaginalis, Enterococcus faecium, Klebsiella pneumonia, Acinetobacter calcoaceticus, Hemophilus influenza, Branhamella catarrhalis, E.coli, Neisseria meningitidis, Candida albicans, Chlamydia trachomatis, Rotavirus

LITERATURE REFERENCES

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3. Hazell, SL, et al. Campylobacter pyloridis and gastritis I: Detection of urease as a marker of bacterial colonization and gastritis. Amer. J. Gastroenterology. (1987), 82(4): 292-96.
4. Cutler AF. Testing for Helicobacter pylori in clinical practice. Am j. Med. 1996; 100:35S-41S.
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GLOSSARY OF SYMBOLS

Table mapping symbols to their meanings: REF (Catalog number), Temperature limitation, LOT (Batch code), IVD (In vitro diagnostic medical device), Use by, Manufacturer, Do not reuse.