TEST IT
for healthy generations

INSTRUCTION FOR USE
H.pylori Ag Test
For *Helicobacter pylori* Antigen Detection in Feces

in vitro diagnostic test

Only for professional *in vitro* diagnostic use

Product Code: TIHP03

H. pylori Ag Test detects *H. pylori* antigens in human feces

BACKGROUND INFORMATION

H. pylori is small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum. It is implicated in the etiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcer, non-ulcer dyspepsia and active and chronic gastritis. Both invasive and non-invasive methods are used to diagnose *H. pylori* infection in patients with symptoms of gastrointestinal disease. Specimen dependent and costly invasive diagnostic methods include gastric or duodenal biopsy followed by urease testing (presumptive), culture and/or histologic staining. *H. pylori* chronically infects the stomach of more than half of the human population and represents the major cause of gastroduodenal pathologies. However, only 10 - 20 % of *H. pylori* infected patients develop severe diseases, such as peptic ulcer, gastric cancer, and lymphoma, during their lifetime. This fact suggests that the type of innate and acquired immune response to *H. pylori* may represent an important factor able to influence the outcome of the infection towards protection, evasion, or pathology. Differences may occur in the mode of transmission of *H. pylori* between developed and developing countries: direct human-to-human contacts have been suggested as the primary route in the former while the fecal-oral route, also, through contaminated water, in the latter. A very common approach to the diagnosis of *H. pylori* infection is the serological identification of specific antibodies in infected patients. The main limitation of serological test is the inability to distinguish current and past infections. Antibody may be present in the patient's serum long after eradication of the organisms. HpSA (*H. pylori* Stool Antigen) testing is gaining popularity for diagnosis of *H. pylori* infection and also for monitoring the efficiency of the treatment of *H. pylori* infection.

INTENDED USE

H.pylori Ag Test is a rapid immunochromatographic assay for qualitative detection of *H. pylori* antigens in human feces samples to aid in the diagnosis of *H. pylori* infection.

REAGENTS

Anti- *H. pylori* antibodies coated particles and anti- *H. pylori* antibodies immobilized on the membrane.

METHOD

H. pylori Ag Test is a qualitative, immunochromatographic assay for detection of *H. pylori* antigens in human feces samples. "T" test area of this test is pre-coated with anti-*H. pylori* antibodies. While performing the test; sample dropped to the sample well reacts with the particles coated with anti-*H. pylori* antibodies. This complex migrates to the other end of the membrane by capillary action. If there are *H. pylori* antigens at detectable level in the sample, they bind to anti-*H. pylori* antibodies in the "T" test area and creates a visible, colored signal that means the test result is positive. If the sample does not contain *H. pylori* antigens at detectable level, colored line does not appear in the "T" test area. This means the test result is negative. As a procedural control, colored line always appears in the "C" control area indicating that proper volume of sample has been introduced and membrane wicking has occurred.

PRECAUTIONS AND LIMITATIONS

1. For professional and *in vitro* diagnostic use only.
2. Read this insert completely and carefully prior to use of the test. Test must be performed in strict accordance with these instructions to obtain accurate results.
3. Do not use test kit beyond expiry date. The test device is single use. Do not reuse.
4. The test device should remain in its original sealed pouch until usage. Do not use the test if the seal is broken or the pouch is damaged.
5. Wear disposable gloves while performing the test.
6. Use a new pipette for each sample.
7. This test kit should be handled only by adequately qualified personnel trained in laboratory procedures and familiar with their potential hazards. Wear appropriate protective clothing, gloves and eye/face protection and handle appropriately with the requisite Good Laboratory Practices.
8. All patient samples should be handled as taking capable of transmitting disease into consideration. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
9. 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.
10. This test will indicate only the selectively total *H. pylori* antigens in the sample, and should not be used as the only basis for the diagnosis of *H. pylori* infection.

As with all diagnostic tests, it should be kept in mind that an identification diagnosis can't be based on a single test result. Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings.

11. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *H. pylori* infection.

STORAGE

Test device should be kept away from direct sunlight, moisture, heat and radiation sources. Store at 4 - 30°C (39 - 86°F). Do not freeze.

The test in the original packaging retains stable until expiry date at storage conditions. The test device should be used in maximum one hour after the foil is opened.

Kit components : Test cassettes, pipettes, sample collection tubes with dilution buffer and instructions for use.

Additional materials required but not provided : Sample collection containers, centrifuge and timer.

Additional materials recommended but not provided : Micropipettes to deliver mentioned amount of sample in the test procedure, negative and positive control materials.

TEST PROCEDURE

Bring the tests, dilution buffer and samples to room temperature. Take the test out of its pouch.

1. **Feces samples:**

Feces sample must be collected in clean, dry, waterproof container containing no detergents, preservatives and transport media. Take 1 - 2 ml or 1 - 2 g feces sample to the container to collect sufficient quantity of antigen (if present). Best results will be obtained if the assay is performed with the fresh sample immediately after collection. Collected samples may be stored at -20°C for long term storage.

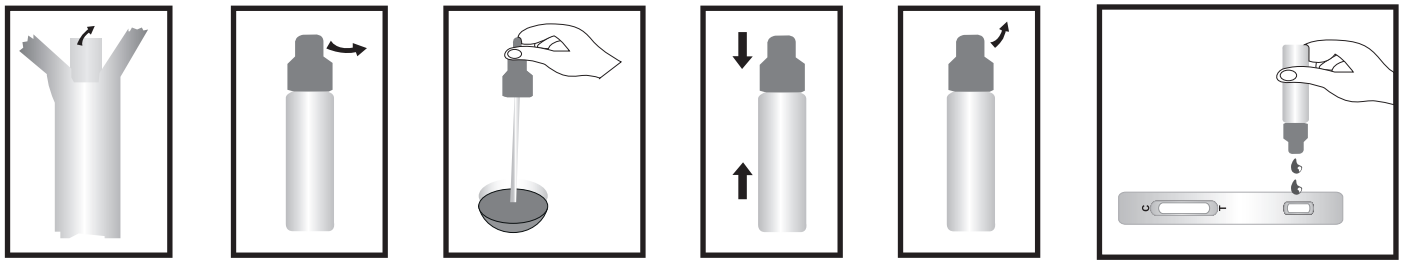
2. **To process fecal samples:**

a. For solid samples ; Unscrew the cap of the sample collection tube. Stab the sample collection applicator randomly into the fecal sample in at least 3 different sites to collect approximately 50 mg of feces Screw the applicator to the sample collection tube with the sample on it.

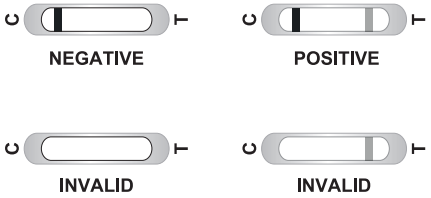
b. For liquid samples ; Hold the pipette vertically and draw feces sample into the pipette. Put 3 drops (~75 µl) of sample in the sample collection tube.

3. Screw the cap of the sample collection tube and shake well to mix the sample and the dilution buffer. Wait for two minutes.
4. Hold the sample collection tube upright and open the cap. Transfer 2 drops of extracted sample to the sample well of the cassette. Avoid the formation of any air bubbles.
5. Results should be read at 10 minutes as shown below. Results forming after 20 minutes should be regarded as invalid.

NOTE: If the extracted sample does not migrate in the test because of the particles, centrifuge the extracted sample in the sample collection tube. Then collect 80 µl supernatant and dispense it to the sample well of a new test device and follow the instruction from step 5.



INTERPRETATION OF RESULTS



Negative : Only one colored line is visible in "C" area.
Positive : Two colored lines are visible in "C" and "T" areas.
Low concentration of *H. pylori* antigen may cause a faint line in "T" area.
Even such a faint line in "T" area should be regarded as "positive".
Invalid : No colored line is visible or only one colored line is visible in "T" area; test should be repeated using a new test device.

QUALITY CONTROL

Tests have built in procedural quality control features. When the test is complete, the user will see a colored line in the "C" area of the test on negative samples and a colored line in the "T" and "C" area on positive samples. The appearance of the control "C" line is considered as an internal procedural control. This line indicates that sufficient volume of sample was added as well as valid test result. It is recommended that a negative control and a positive control be used to verify proper test performance as an external control. Users should follow appropriate federal, state and local guidelines concerning the external quality controls.

PERFORMANCE EVALUATION

H. pylori Ag Test has been evaluated with the samples from a population of symptomatic and asymptomatic individuals. Endoscope based methods are used as a reference and following results are obtained:

Sensitivity : 99,9 % Specificity : 99,9 % + Predictive V : 99,9 % - Predictive V : 99,9 %

		Reference	
		+ Result	− Result
Test	+ Result	110	0
	− Result	0	95

Intra Assay

Within-run precision of the same test has been confirmed with 100 replicates of negative, low positive and high positive samples. Negative, low positive and high positive values were correctly determined for each trial.

Inter Assay

Between-run precision of the same test has been confirmed with 10 independent assays with the same negative, low positive and high positive samples. Negative, low positive and high positive values were correctly determined for each trial.

CROSS REACTIVITY

Cross reactivity has been tested with below samples (1,0 X 10^9 microorganism/ml), no cross reactivity was found with the *H. pylori* Ag Test.

Staphylococcus aureus	*Proteus mirabilis*	*Neisseria gonorrhea*
Pseudomonas aeruginosa	*Acinetobacter spp*	*Group B Streptococcus*
Enterococcus faecalis	*Salmonella choleraesius*	*Proteus vulgaris*
Group C Streptococcus	*Gardnerella vaginalis*	*Enterococcus faecium*
Klebsiella pneumoniae	*Acinetobacter calcoacetius*	*Hemophilus influenzae*
Branhamella catarrhalis	*E.coli*	*Neisseria meningitidis*
Candida albicans	*Chlamydia trachomatis*	*Rotavirus*

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CE

Manufacturer
Consult instruction for use
Attention, see instruction for use
IVD *In vitro* diagnostic medical device
For single use only
Number of test
REF Catalog number
Storage temperature
LOT Lot number
Expiry date