



INSTRUCTION FOR USE

H. Pylori Ab Test

For *Helicobacter pylori* Antibody
Detection in Whole Blood / Serum / Plasma

in vitro diagnostic test

Only for professional *in vitro* diagnostic use

Product Code: THP02

H. pylori Ab Test detects *H. pylori* antibodies generated against *H. pylori* antigens in human whole blood, serum or plasma

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.

Non-invasive techniques include urea breath test, which requires expensive laboratory equipment and moderate radiation exposure and serological methods. Individuals who have *H. pylori* infection develops *H. pylori* antibodies that have strongly confirmed with histological results.

INTENDED USE

H. pylori Ab Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies generated against *H. pylori* antigens in human whole blood, serum or plasma samples to aid in the diagnosis of *H. pylori* infection.

REAGENTS

H. pylori antigen coated particles and anti-human IgG antibodies immobilized on the membrane

METHOD

H. pylori Ab Test is a membrane based immunochromatographic assay that detects antibodies generated against *H. pylori* antigens in human whole blood, serum or plasma. Anti-human IgG antibodies are immobilized in the "T" test area of the device. Sample dropped to the sample of the cassette reacts with *H. pylori* antigen coated particles. This complex migrates through the membrane and reacts with anti-human IgG antibodies immobilized on the membrane. If there are antibodies generated against *H. pylori* antigens in the sample a colored test line will appear in the "T" test area and this line indicates a positive test result. If the sample does not contain antibodies generated against *H. pylori* antigens a colored line will not appear in the "T" test area, indicating a negative test result. As a procedural control, a 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. Do not use test kit beyond expiry date. The test device is single use. Do not reuse.
3. 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.
4. Wear disposable gloves while performing the test.
5. Use a new dropper for each sample.
6. 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.
7. This test will indicate only the presence or absence of *H. pylori* antibodies 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.
8. 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, droppers, diluent (for whole blood samples only) and instructions for use.

Additional materials required but not provided : Sample collection tube, centrifuge, lancet (for only fingerstick whole blood), heparinized dispensing bulbs and capillary tubes (for only fingerstick whole blood) and timer.

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

SAMPLE COLLECTION AND PREPARATION

The test can be performed using whole blood, serum or plasma. To avoid hemolysis, serum or plasma should be separated from blood as soon as possible.

For Whole Blood Samples: Test should be performed immediately with whole blood samples. Otherwise, whole blood samples should be stored at 2 - 8 °C with anticoagulants (EDTA, heparin, citrate should be used) to avoid coagulation until they are being tested in a period of 2 days after collection.

For Serum Samples: Collect blood into a collection tube without anticoagulant, leave to settle for 30 minutes for blood coagulation and then centrifuge the blood. At the end of centrifuge period remaining supernatant is used as serum.

For Plasma Samples: Collect blood into a collection tube with anticoagulants (EDTA, heparin, citrate should be used) to avoid coagulation of blood sample and then centrifuge the blood. At the end of centrifuge period supernatant is used as plasma.

Do not use turbid, hemolyzed samples. If the sample cannot be tested on the day of collection, store the serum, plasma samples in a refrigerator or freezer. Do not freeze and thaw the serum, plasma samples repeatedly. Do not freeze whole blood sample. Bring the samples to room temperature before testing. Frozen samples must be completely thawed and mixed well prior to testing. Turbid test samples should be centrifuged. Using of frozen and thawed samples should be avoided whenever possible, due to the blocking of the membrane by the debris.

TEST PROCEDURE

1. Bring the tests and samples to room temperature. Take the test out of its pouch.

2. **For Whole Blood Samples :** Draw whole blood into dropper and put 3 drops (100 µl) into the sample well of the cassette. Immediately after, 1 drop of diluent is added into the sample well and allowed to soak in.

For Serum / Plasma Samples : Draw serum / plasma into dropper and put 3 drops (100 µl) into the sample well of the cassette. Do not use diluent for serum / plasma samples. Avoid the formation of any air bubbles.

3. Depending on the *H. pylori* antibody concentration in the sample, the test can react even in 5 minutes. Results should be read at 10 minutes as shown below. Results forming after 20 minutes should be regarded as invalid.

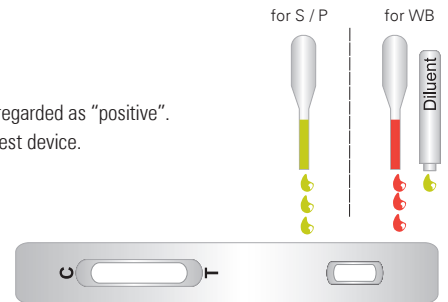
INTERPRETATION OF RESULTS

Negative: Only one colored line is visible in "C" area, indicating that *H. pylori* antibody does not exist.

Positive: Two colored lines are visible in "C" and "T" areas, indicating that *H. pylori* antibody exists.

Low concentration of *H. pylori* antibody 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 Ab Test has been evaluated with serum and plasma samples from a population of symptomatic and asymptomatic individuals who had endoscopic examination. ELISA methods are used to compare *H. pylori* Ab Test and following results are obtained.

Sensitivity : 98,7 % Specificity : 93,2 % + Predictive V : 96,8 % - Predictive V : 97,2 %

		Reference	
		+ Result	- Result
Test	+ Result	305	10
	- Result	4	139

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 20 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

Serum samples involving known amounts of *C. jejuni*, *C. fetus*, *C. coli* and *E. coli* have been tested with *H. pylori* Ab Test. No cross-reactivity has been observed.

INTERFERENCES












H. pylori Ab Test tested with visibly hemolyzed and lipemic samples, as well as samples containing high bilirubin levels. No interference was detected in samples containing up to 1.000 mg/dl hemoglobin, up to 1.000 mg/dl bilirubin and up to 2.000 mg/ml human serum albumin.

Hemolytic samples should not be used since they can cause to invalid or false results.

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