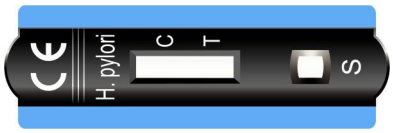
H. PYLORI TEST
008V400

ulti med H. pylori Test Cassette for the detection of antibodies to Helicobacter pylori in whole blood, serum or plasma specimens



INTENDED USE

The **ulti med Helicobacter pylori Test** is a rapid chromatographic immunoassay for the qualitative detection of antibodies to H. pylori in whole blood, serum, or plasma to aid in the diagnosis of H. pylori infection. It is a rapid assay for determination of anti-H. pylori antibodies of all isotypes (IgG, IgM, IgA, etc.).

SUMMARY

H. pylori is a 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 histological staining. Non-invasive techniques include the urea breath test, which requires expensive laboratory equipment and moderate radiation exposure, and serological methods. Individuals infected with H. pylori develop serum antibodies which correlate strongly with histologically confirmed H. pylori infection.

PRECAUTIONS

The ulti med H. pylori Test devices should be stored at 4-30°C. The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration.

MATERIALS PROVIDED

- H. pylori Test cassette in foil pouch (20 per kit box)
- Heparin tubes (20 per kit box)
- Disposable sample dropper
- Buffer (1 per kit box)
- Instructions (1 per kit box)

MATERIALS REQUIRED, BUT NOT PROVIDED

- Stop watch

SPECIMEN COLLECTION AND PREPARATION

Whole Blood specimen collection: Use the provided heparin tube to collect a blood specimen or collect an anticoagulated blood sample by using heparin as the anti-coagulant.

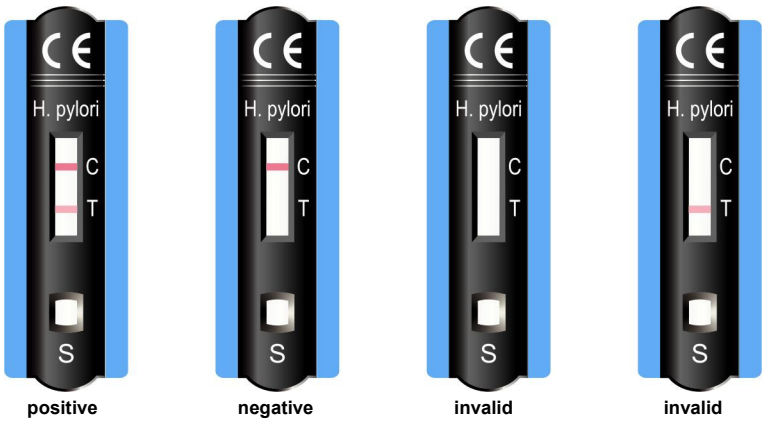
WARNINGS

- For in vitro diagnostic use only.
- Do not eat or smoke while handling specimens.
- Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
- Avoid splashing or aerosol formation.
- Clean up spills thoroughly using an appropriate disinfectant.
- Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
- Do not use the test kit if the pouch is damaged or the seal is broken.

PROCEDURE

1. Remove the test cassette from the foil pouch, and place it on a flat, dry and clean surface.
2. Hold the sample dropper above the test cassette and add 1 hanging drop into the Sample Well (S). After the drop is absorbed into the Sample Well, add 2 drops of buffer into the Sample Well. As the test begins to work, you will see purple coloured front move across the Result Window in the centre of the test cassette.
3. Interpret test results after 10 minutes. Do not read it after more than 15 minutes.

Caution: The above waiting time is based on reading the test results at room temperature of 15 to 30°C. If your room temperature is significantly lower than 15°C, then the waiting time should be properly increased.



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INTERPRETATION OF RESULTS

- A coloured line will appear in the section of the result window marked with "C" to show that the test is working properly. This line is the Control Line.
- The section of the result window marked with "T" indicates the test results. If another coloured line appears here, this line is the Test Line.

Positive Result: The presence of two coloured lines ("T" line and "C" line) in the result window regardless of which line appears first indicates a positive result (Figure 1). **Note:** Generally, the higher the analyte level in the specimen, the stronger the "T" line colour will be. When the specimen analyte level is close to but still within the sensitivity limit of the test, the colour of the "T" line will be very faint.

Negative Result: The presence of only one purple colour line in the result window indicates a negative result (Figure 2).

Invalid: If after performing the test no purple coloured line is visible in the Result Window, or only one at "T", the result is considered invalid (Figure 3 and 4). Some causes of invalid results: not following the directions correctly or the test is beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit.
Note: A positive result will not change once it has been established at 10 minutes. However, in order to prevent any incorrect results, the test should not be interpreted after more than 15 minutes.

LIMITATIONS OF THE TEST

Content of this kit is for the use in the qualitative detection of H. pylori-specific antibodies and does not indicate the titre of the antibody in the sample. The test should be used only to evaluate patients with clinical signs and symptoms suggestive of gastrointestinal disease. The performance characteristics of this test have not been established in a pediatric population.

Although the test is very accurate in detecting antibodies to H. pylori, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. 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.

SPECIFICITY AND INTERFERENCE STUDY

1. Specificity study: The ability of the H. pylori Test to specifically detect H. pylori was challenged through cross reaction studies on serum samples containing known other closely related microorganisms such as Camplyobacter fetus, Campylobacter jejunii and E. coli. Serum samples that are negative to the H. pylori Test were spiked with various concentration levels of the above microorganisms. These samples were tested on the H. pylori Test kit. Each microorganism had 10 runs of the H. Pylori test. A total 30 test results indicated H. pylori Test does not cross-react with the above microorganisms.
2. Interference Study: Potentially interfering chemicals such as pain medication, lipids, haemoglobin, bilirubin and glucose were supplemented to negative normal serum specimens. Above baseline specimens as well as H. Pylori positive specimens were then analyzed. All interference studies indicated none of the above substances interfered with the H. pylori test procedure. Baseline serum samples with supplementation and potentially interfering substances gave consistently negative test results. The serum sample positive to H. Pylori scored consistently positive.

REFERENCES

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	Manufacturer		Contents sufficient for <n> tests
IVD	For in vitro diagnostic use only	LOT	Lot. no.
	For single use only		Use by
	Read instructions for use		Store at

Manufacturer:

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