BioTina GmbH
H. PYLORI CASSETTE
Cat. No.: R 5006

A rapid one-step, visual test for the detection of H. pylori infection. For professional In Vitro diagnostic use only.

INTENDED USE
The H. Pylori Cassette Test is a rapid one step, visual test for the qualitative detection of specific IgG to Helicobacter pylori in human serum. This kit is intended as an aid in the diagnosis of H. pylori infection in patients with gastrointestinal symptoms. For in vitro diagnostic use only.

SUMMARY
Gastritis and peptic ulcers are one of the most common human diseases. Since the discovery of H. pylori (Warren & Marshall, 1983), many reports have suggested that this organism is one of the major cause of ulcer diseases (Anderson & Nielsen, 1983; Hunt & Mohamed, 1995; Lambert et al., 1995). Although the exact role of H. pylori is not fully understood yet, eradication of H. pylori has been associated with the elimination of ulcer diseases. The human serological responses to infection with H. pylori have been demonstrated (Varia & Holton, 1989; Evans et al., 1989). The detection of the specific IgG antibodies to H. pylori has been shown to be an accurate method for detection of H. pylori infection in symptomatic patients. H. pylori may colonize in some asymptomatic persons. A serological test may be used either as an adjunct to endoscopy or as an alternative measure in symptomatic patients.

PRINCIPLE
The H. Pylori Cassette Test is intended for use in the detection of antibodies specific to H. pylori in serum. Proper use of the test permits detection of H. pylori infection in symptomatic patients. This information can be used by the physician and the patient for ulcer disease management. The H. Pylori Cassette Test has been designed to detect the H. pylori infection through visual interpretation of color development in the test device, which is a sandwich solid phase dye conjugate non-enzyme immunooassay. The membrane was precoated with H. pylori antigens on the test band region and goat anti-mouse antibody on the control band region. During the test the diluted patient serum is allowed to react with a colored conjugate (H.pylori antigens-colloid gold conjugate) which was predried on the pad inside the test cassette. The mixture then moves on the membrane chromatographically by a capillary action. When H. pylori specific IgG antibodies are present in a sample, a color band with a specific antibody-antigen-colored conjugate complex will form at the test region of the membrane. On the other hand, a color band will always appear at the control region. This control band serves as a procedural indicator for the proper functioning of the device. A distinct color development in the test band region indicates a positive result and absence of a color band in the test region suggests a negative result.

STORAGE AND STABILITY
The test kit is to be stored at refrigeration (2-8°C) or room temperature (up to 30°C) in the sealed pouch for the duration of the shelf life.

PRECAUTIONS
- FOR IN VITRO USE ONLY.
- For professional use only.
- Do not use the kit beyond expiration date.
- Do not open the Test Cassette Foil Pouch until you are ready to perform the test.
- Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.

REAGENTS AND MATERIALS SUPPLIED
- Test device: Each test cassette is containing a test strip with H. pylori antigen coated membrane and a colored antigen pad.
- Dilution buffer: Phosphate buffered saline with Tween 20 and preservative.

MATERIAL REQUIRED BUT NOT PROVIDED
- Specimen collection container.
- Timer.

TEST PROCEDURE
Test device, patient’s samples, and controls should be brought to room temperature (20-30°C) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the test device from its protective pouch (bring the device to room temperature before opening the pouch to avoid condensation of moisture on the membrane). Label the device with patient or control identification.

2. Dilute 20 μl serum sample in 180 μl dilution buffer and add 120 μl (3 drops) into the sample well of the device. Alternatively, add 10 μl serum sample (1 drop using the pipette supplied with the test) into the sample well first and then add 3 drops of dilution buffer. Avoid dropping any solution in the observation window.

3. Read the result within 15 minutes after the addition of sample.
INTERPRETATION OF RESULTS

Negative: only one red colored band appears on the control line region. No apparent red-colored band is visible on the test line region.

Positive: in addition to the control band, a distinct red colored band also appears on the test line region.

Invalid: when no colored band appears on either region, the test should be voided since an improper test procedure or deterioration of reagents probably occurred.

QUALITY CONTROL

The procedural control is included in the test. A colored band appearing on the control region of the membrane indicates proper performance and reactive reagents.

EXPECTED VALUES

The majority of individuals exposed to H. pylori possess IgG to the organism. It is reported that H. pylori is universally distributed and an estimated 50% of the world’s populations are colonized by H. pylori (Lambert et al., 1995). The presence of H. pylori antibodies is a function of age, race, geography and clinical condition. A relatively large proportion of patients who have positive levels of antibody are asymptotic, even through they are colonized with the H. pylori. Therefore, antibody levels do not necessarily correlate with the severity of clinical symptoms (Tytgat & Rauws, 1989).

LIMITATIONS

1. This test is to be used for the qualitative detection of IgG antibody to H. pylori.
2. This kit should be used for symptomatic individuals with gastrointestinal disorders. Diagnosis of gastritis and/or peptic ulcers should be made by confirmation with other clinical findings.
3. A positive result suggests the presence of IgG to H. pylori and does not allow one to distinguish between active infection and colonization by H. pylori. It does not necessarily indicate that a gastrointestinal disease is present.
4. A negative result does not rule out infection by H. pylori because the antibody to H. pylori may be absent or may not be present in sufficient quantity to be detected.
5. Serum samples from patients infected with C. jejuni may produce a low level of cross-reactivity in this test.

REFERENCES