H. Pylori # 4D400

Rapid test for the detection of Antibodies against H. Pylori in human serum, plasma or whole blood

INTENDED USE
The GECKO H. Pylori Cassette Test is a rapid, visual test for the qualitative detection of antibody to Helicobacter pylori in human serum, plasma or whole blood. 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 causes 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 symptoms. The human serological responses to infection with H. pylori have been demonstrated (Varia & Holton, 1989; Evans et al., 1989). The detection of the specific antibodies to H. pylori has been shown to be an accurate method for detection of H. pylori infection in symptomatic patients. H. pylori may colorize in some asymptomatic persons. A sero-logical test may be used either as an adjunct to endoscopy or as an alternative measure in symptomatic patients.

PRINCIPLE
The GECKO 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 GECKO 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 immunoassay. The membrane was precoated with H. pylori antigens on the test line region (T). During the test the diluted patient serum is allowed to react with a colored conjugate (H.pylori antigens-dye conjugate) which was submitted on the pad inside the test cassette. The mixture then moves on the membrane chromatographically by a capillary action. If H. pylori specific antibodies are present in a sample, a colored line with a specific antibody-antigen-colored conjugate complex will form at the test line region of the membrane.

On the other hand, a color line will always appear at the control region (C) using another antigen-antibody reaction. This control line serves as a procedural indicator for the proper function of the device. It shows that the test procedure has been correct and membrane wicking has occurred. A distinct color development in the test line region (T) indicates a positive result and absence of a color line in the test line region (T) 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
• Do not touch the reaction zone of the device to avoid contamination!
• Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
• Evaluate the test result after 15 minutes.
• Store and transport the test device always at 2-30°C (36-86°F)
• Humidity and high temperature can adversely affect results.

REAGENTS AND MATERIALS SUPPLIED
• single pouched test devices
• Dilution buffer

MATERIAL REQUIRED BUT NOT PROVIDED
• Specimen collection container.
• Lancet
• Timer.

SPECIMEN COLLECTION AND HANDLING
• The GECKO H. Pylori Cassette Test (Whole Blood/ Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum, or plasma.
• Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens. There are no limitations concerning the usage of any anticoagulants.
• Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below 20°C.
• Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
• Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
• If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

TEST PROCEDURE
Test device, buffer and patient’s samples, 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. Add app. 20 µl serum, plasma or whole blood sample (1 drop using the pipette supplied with the test) into the sample well first and then add 2-3 drops of dilution buffer. Avoid dropping any solution in the observation window. Start the timer!
3. Read the result within 15 minutes after the addition of sample. Do not read results after 30 minutes.
INTERPRETATION OF RESULTS

**Negative result:** Only one red colored line appears on the control line (C) region. No apparent red-colored line is visible on the test line region (T).

**Positive result:** In addition to the control line, a distinct red colored line also appears on the test line region. Note: The color intensities of the lines might vary!

**Invalid result:** If no control line appears in the C-region the test is not conclusive and must be interpreted as invalid. The absence of the control line might indicate an error. Please repeat the test with a new test card paying special attention to the instructions. If the problem persists contact your manufacturer.

QUALITY CONTROL
An internal procedural control is included in the test. A reddish control line appearing in the Control region (C-region) of the membrane indicates proper performance of the test. Good laboratory practise (GMP) recommends the use of external controls for the indication of the proper function of the test set.

EXPECTED VALUES
The majority of individuals exposed to *H. pylori* possesses antibodies. It is reported that *H. pylori* is universally distributed and as estimated value 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 antibodies are without any symptoms, even though they are colonized with the *H. pylori*. Therefore, antibody levels do not necessarily correlate with the severity of clinical symptoms (Tytgat & Rauws, 1989).

SPECIFICITY
The GECKO *H. Pylori* Cassette Test should not give positive results with antibodies against similar respectively closely related bacteria like *Campylobacter coli* (ATCC 33559), *Campylobacter fetus* (ATCC 27374), and *Escherichia coli*. Serum samples from patients infected with *C. jejuni* (*Campylobacter jejuni* (ATCC 33560)) may produce a low level of cross-reactivity in this test.

The GECKO *H. Pylori* Cassette Test should not be influenced by the use of visibly hemolyzed, lipemic and icteric samples as well as from human hemoglobin, bilirubin or albumin.

LIMITATIONS
1. This test is to be used for the qualitative detection of 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 antibody 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 quantities to be detected.
5. Serum samples from patients infected with *C. jejuni* may produce a low level of cross-reactivity in this test.

REFERENCES

SYMBOLS:

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