HELICOBACTER PYLORI CARD Ab

For *in Vitro* diagnostic use

Immunochromatographic test for the detection of anti-Helicobacter pylori antibodies in human serum, plasma or whole blood

INTENDED USE

The Helicobacter Pylori Card Ab is a simple one step immunochromatographic assay for the rapid, qualitative detection of antibodies to Helicobacter Pylori in human plasma, serum or whole blood. The Helicobacter Pylori Card Ab is intended for professional use as an aid in the diagnosis of Helicobacter Pylori infections.

INTRODUCTION

Helicobacter pylori is a corkscrew-shaped, gram-negative rod that lives in the mucous layer of the stomach. *H. pylori* infection is now accepted as the most common cause of gastritis, and is etiologically involved in gastric ulcer, duodenal ulcer, gastric adenocarcinoma and primary gastric *B*-cell lymphoma. The organism is very common, infected at least half of the world's population. *H. pylori* infection is typically acquired in childhood. Once acquired, infection persists chronically, probably continuing in the stomach throughout life. The damage to gastric structure and function of stomach is constant and direct. Approximately one in six of *H. pylori* infection develops peptic ulcer disease and a small portion of *H. pylori* infection leads to gastric cancer. The diagnostic tests for *H. pylori* can be classified into two categories: Invasive and Non invasive tests. Direct detection by invasive test procedures requires an endoscopy and biopsy specimens from antrum and stomach body. The presence of *H. pylori* is then confirmed by direct culture, histological examination or rapid urease test. The endoscopy and biopsy specimens offer direct detection of active *H. pylori* infections. Although the procedure is highly specific and high positive predictive value, the cost and discomfort to the patients are very high. The most widely available noninvasive test is probably the serological based test. The serology test detects *H. pylori* specific IgG antibody in patient serum with current or prior infection. Serology test is a simple, convenient test with relative high sensitivity. The main limitation of serology test is the inability to distinguish current and past infections. Antibody may be present in the patient's serum long after eradication of the organism. The urease breath test (UBT) with 14C or 13C labeled urea, is a non invasive test based on the urease activity of the organism. UBT detects active *H. pylori* infection and is highly sensitive and specific. The UBT requires a high density and active bacteria and should not be performed until 4 weeks after therapy to allow residual bacterial to increase to a sufficient number for detection. Helicobacter Pylori Card Ab is an immunochromatographic assay that uses double antigen sandwich technology to detect the presence of *H. pylori* antibody in human blood specimens. The test is simple and easy to perform and the test results can be visually interpreted within 10 minutes

PRINCIPLE OF THE ASSAY

The Helicobacter Pylori Card Ab is rapid assay for determination of anti-H. Pylori antibodies of all isotypes (IgG, IgM, etc.). The Helicobacter Pylori Card Ab test cassette has a letter "T" and "C" as "Test Line" and "Control Line" on the surface of the case. Helicobacter pylori Card Ab employs chromatographic lateral flow test device in a cassette or strip format. Colloidal gold conjugated H. pylori antigens (Au-Ag) are dry-immobilized at the end of nitrocellulose membrane strip. H. Pylori antigens are bond at the Test Zone (T) When the sample is added, it migrates by capillary diffusion rehydrating the gold conjugate. If anti-H. pylori antibodies present in sample, Antibodies will bind with the gold conjugated antigens forming particles. These particles will continue to migrate along the strip until the Test Zone (T) where they are captured by H. pylori antigens generating a visible red line. If there are no anti-H. Pylori antibodies in sample, no red line is formed in the Test Zone (T). A built-in control line will always appear in the Control Zone (C) when the test has performed properly, regardless of the presence or absence of anti-H. pylori antibodies in the specimen.

MATERIALS PROVIDED

The Helicobacter Pylori Card Ab test kit contains the following items to perform the assay:

1. H. Pylori test card with disposable sample dropper.
2. Instruction for use.

STORAGE OF THE KIT

The Helicobacter Pylori Card Ab should be stored at room temperature 4-30ºC (40-86ºF). 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.

SPECIMEN COLLECTION AND STORAGE

Serum / plasma/ Whole Blood, collect an anti-coagulated blood sample (Heparin, EDTA and Oxalate). May be stored at 2-8°C up to 3 days For long-term storage, freeze the specimen at -20°C for 3 months or -70°C for longer periods. Repeated freezing and thawing of the specimen should be avoided. Do not use haemolysed, clotted, contaminated, lipemic and viscous/turbid specimen. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.

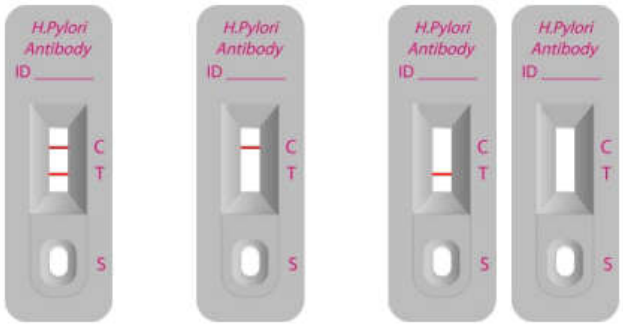
Fresh serum/plasma is preferable. Serum/plasma may be stored at 2-8°C up to 3 days in case of delay in testing. For long-term storage, freeze the specimen at -20°C for 3 months or -70°C for longer periods. The test works best on fresh whole blood samples. If testing cannot be done immediately, Blood samples collected with a suitable anticoagulant such as EDTA or Heparin should be stored at 2-8ºC up to 3 days. Blood samples should not be frozen.
Repeated freezing and thawing of the specimen should be avoided.
Do not use haemolysed, clotted, contaminated, lipemic and viscous/turbid specimen.
Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.
Do not heat inactivate the sample.

PROCEDURE

1. Remove the Card from the foil pouch, and place it on a flat, dry surface. Label the test card with patients identity.
2. Holding the sample dropper and add 3 drops (120-150µL) of specimen into the Sample Well. As the test begins to work, you will see purple/red colour move across the Result Window in the center of the result window.
3. Interpret test results within 10 minutes. A strong positive sample may show result earlier. Do not read result after 30 minutes.

INTERPRETATION OF THE TEST

Positive - The presence of two colour bands ("T" band and "C" band) within the result window regardless of which band appears first indicates a positive result. Note: Generally, the higher the analyte level in the specimen, the stronger the "T" band 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" band will be very faint.
Negative - The presence of only one purple/red colour band ("C" band) within the result window indicates a negative result.
Invalid - If after performing the test no purple/red colour band is visible within the Result Window, the result is considered invalid. 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



POSITIVE **NEGATIVE** **INVALID**

LIMITATIONS OF THE TEST

The content of this kit is for the use in the qualitative detection of H. Pylori-specific IgG and IgM antibodies and does not indicate the titer of the antibody in the sample. The test should be used only to evaluate patients with clinical signs and symptoms suggestive of gastrointestinal disease.

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.

PERFORMANCES OF THE TEST

INTERFERENCE: No interference was found with bilirubin (10 mg/dL), hemoglobin (250 mg/dL), triglycerides (500 mg/dL) or cholesterol (800 mg/dL) on the sensitivity and specificity of the test.

ACCURACY (Specificity and Sensitivity): A panel of 30 positive and 61 negative patient sera was tested with a reference ELISA test. The results are summarized in the following table.

	ELISA H. Pylori Antibody Test		
Helicobacter Pylori Card Ab		Positive	Negative
	Positive	30	2
	Negative	0	65
	Agreement	100%	97%

WARNINGS AND PRECAUTIONS

- For professional and in vitro diagnostic use only.
- Read the instructions carefully before performing the test.
- Do not use kit contents after the expiration date
- Do not eat, drink or smoke while handling specimens.
- Handle all specimens as potentially infectious
- Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
- Avoid splashing or aerosol formation.
- Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infective material. When the assay procedure is complete, dispose specimens after autoclaving them at 121° C for at least 20 min. Alternatively, they can be treated with 0.5% Sodium Hypochlorite for 1-2 hours before disposal
- Do not use the test kit if the pouch is damaged or the seal is broken.

REFERENCES (see Italian version)

IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (EXXX)		Manufacturer		Keep dry	NON STERILE	Non-sterile
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

CONTENT **VQ81650 (20 Test)**

Test Device Card 20 items
Instructions for use 1 item

EDMA (EDMS) CODE 1501049000 CE IVD