Helicobacter pylori

Rapid test for the detection of H.pylori antibody in whole blood, serum, plasma

Product-#: D-HP-W23-002

INTENDED USE

The DIMA® H. pylori Antibody Test Device is a rapid visual immunoassay for the qualitative presumptive detection of specific antibodies to Helicobacter pylori in human whole blood, serum, or plasma specimens. This kit is intended for use as an aid in the diagnosis of H. pylori infection.

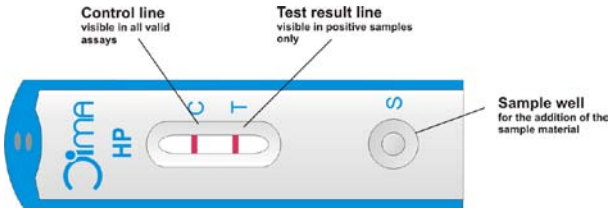
INTRODUCTION

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 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 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 asymptotic persons. A sero-logical test may be used either as an adjunct to endoscopy or as an alternative measure in symptomatic patients.

TEST PRINCIPLE

The DIMA® H. pylori Antibody Test Device detects antibodies specific to *Helicobacter pylori* through visual interpretation of color development on the internal strip. *H. pylori* antigens are immobilized on the test region of the membrane. During testing, the specimen reacts with *H. pylori* antigen conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there are sufficient antibodies to *Helicobacter pylori* in the specimen, a colored line will form at the test region of the membrane. The presence of this colored line indicates a positive result, while its absence indicates a negative result. The appearance of a colored line at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

Set-up of the test Device



REAGENTS AND MATERIALS SUPPLIED

Individually pouched test devices	Each test contains colored conjugates and reactive reagents precoated at the corresponding regions
Disposable pipettes	For adding specimens
Buffer	Phosphate buffered saline with Tween 20 and preservative
Package insert	For operating instructions

MATERIAL REQUIRED BUT NOT PROVIDED

Specimen collection container	For specimen collection
Timer	For timing use
Centrifuge	For preparing serum/plasma specimens

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Care should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

PRECAUTIONS

- For professional in vitro diagnostic use only!
- Do not use the kit beyond expiration date.
- Read the instructions carefully before performing the test.
- Do not use if pouch was damaged, because the test is humidity-senstive.
- Do not open the foil pouch until you are ready to perform the test.
- Do not use twice!
- Do not eat, drink or smoke in the area where the specimen or devices are handled.
- All patient samples should be treated as if capable of transmitting disease. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Do not pipette reagent by mouth!
- Do not spill solution into the reaction zone!
- Do not touch the reaction zone of the device to avoid contamination!
- Do not interchange or mix reagents from different lots.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Store and transport the test device always at 2-30°C (36°-86°F)
- Humidity and high temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.
- By proper handling and following the standard procedures the test kit don´t cause any danger.

SPECIMEN COLLECTION AND STORAGE

- The DIMA® H. pylori Antibody Test Device is intended for use with human whole blood, serum, or plasma specimens only.
- Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave 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.
- Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, hemolysed, heat treated and contaminated specimens may cause erroneous results.

TEST PROCEDURE

Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed within one hour.
2. Transfer 1 drop of specimen (approximately 25 µl) to the specimen well (S) of the device with the provided disposable pipette, then add 3 drops of buffer and start the timer.
   OR
   Allow 1 drop of fingerstick whole blood specimen (approximately 25 µl) to fall into the center of the specimen well (S) of the device, then add 3 drops of buffer and start the timer.
   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.
   As the test begins to work, color will migrate across the membrane.
3. Wait for the colored line(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

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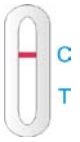
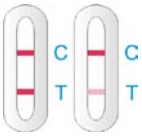
INTERPRETATION OF RESULTS

Negative Result:



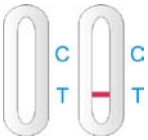
Only one colored line appears, in the control region (C). No colored line appears in the test region (T). A negative result indicates that the specimen contains no *H.pylori*-antibodies.

Positive Result:



Two colored lines appear on the membrane. One line appears in the control region (C) and another line appears in the test region (T). A positive result indicates that *H.pylori*-antibodies were been detected.

Invalid Result:



Control line fails to appear. Results from any test which has not produced a control line at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and please contact the local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region (T) should be considered positive. Please note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF PROCEDURE

- The DIMA® H. pylori Antibody Test Device is for professional *in vitro* diagnostic use, and should only be used for the qualitative detection of *H. pylori* antibodies. No meaning should be inferred from the color intensity or width of any apparent lines.
- This test should be used for symptomatic individuals with gastrointestinal disorders. Diagnosis of gastritis and/or peptic ulcers should be based on test results in conjunction with other clinical and laboratory findings.
- A positive result suggests only the presence of antibodies specific to *H. pylori*, and does not distinguish between active and past infections. A positive result is not necessarily indicative of gastrointestinal disease.
- 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 rule out the possibility of *H. pylori* infection, as antibodies to *H. pylori* may be present below the minimum detection level of the test.
- Specimens from patients infected with *C. jejuni* may exhibit a low level of cross-reactivity in this test.

PERFORMANCE CHARACTERISTICS

Expected values

The majority of individuals exposed to *H. pylori* possess antibodies against *H. pylori*. 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 through they are colonized with the *H. pylori*. Therefore, antibody levels do not necessarily correlate with the severity of clinical symptoms (Tytgat & Rauws, 1989).

Relative Sensitivity and Specificity

The relative sensitivity and the relative specificity of the DIMA® H. pylori Antibody Test Device were determined against another commercially available rapid test and also against an ELISA methodology. The results are shown below:

DIMA® H. pylori Antibody Test Device vs 2nd rapid test

		DIMA® H. pylori Antibody Test Device		
		positive	negative	Total results
2nd rapid test	positive	61	4	65
	negative	16	69	85
Total results		77	73	150

Relative Sensitivity: 93.85% (84.99%-98.30%)*

Relative Specificity: 81.18% (71.24%-88.84%)*

Overall Agreement: 86.67% (80.16%-91.66%)*

*95% Confidence Interval

DIMA® H. pylori Antibody Test Device vs ELISA methodology

		DIMA® H. pylori Antibody Test Device		
		positive	negative	Total results
ELISA	positive	58	9	67
	negative	16	62	78
Total results		74	71	145

Relative Sensitivity: 86.57% (76.03%-93.64%)*

Relative Specificity: 79.49% (68.84%-87.80%)*

Overall Agreement: 82.76% (75.61%-88.52%)*

*95% Confidence Interval

LITERATURE

1. Anderson, L.P. and Nielsen, H., (1993). Peptic ulcer: an infectious disease? Ann. Med. 25: 563-568.
2. Evans, D.J. et al. (1989). A sensitive and specific serologic test for detection *of Campylobacter pylori* infection. Gastroenterology 96: 1004-1008.
3. Hunt, R.H. & Mohamed, A.H. (1995). The current role of *Helicobacter pylori*: eradication in clinical practice. Scand. J. Gastroenterol. 30 suppl 208: 47-52.
4. Lambert, J.R. et al (1995). *Helicobacter pylori*, Scand. J. Gastroenterol. 30 suppl. 208: 33-46.
5. Tytgat, G.N.J. & Rauws, E.A.J. (1989). The role *of Campylobacter pylori* in gastroduodenal diseases: A "believer`s" point of view, Gastroenterol. Clin. Biol., 13: 118-121B.
6. Vaira, D. & Holton, J. (1989). Serum immunoglobulin G antibody levels for *Campylobacter pylori* diagnosis, Gastroenterology 97: 1069-1071.
7. Warren, J.R. & Marshall, B. (1983). Unidentified curved bacillus on gastric epithelium in active chronic gastritis (letters), Lancet 1: 1273-1275.

SYMBOLS

IVD	For *in-vitro* diagnostic use only	2	For single use only
Σ	Content		Expiry date
LOT	Lot number		Storage temperature
	Manufacturer		Carefully read package insert

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