LIMING BIO

H. pylori Antibody Rapid Test Device

REF	502010	**Specimen:** Whole Blood/ Serum/Plasma
Language: English		**Version:** 01
Effective Date: 2009-05		

For professional *in vitro* diagnostic use only.

INTENDED USE

The *StrongStep® H. pylori* Antibody Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of specific IgM and IgG 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 among 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 yet fully understood, 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 IgG antibodies specific to *H. pylori* has been shown to be an accurate method for detecting *H. pylori* infection in symptomatic patients. *H. pylori* may colonize some asymptomatic people. A serological test may be used either as an adjunct to endoscopy or as an alternative measure in symptomatic patients.

PRINCIPLE

The *H. pylori* Antibody Rapid Test Device (Whole Blood/Serum/Plasma) detects IgM and IgG 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 band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

KIT COMPONENTS

Individually packed test devices	Each device contains a strip with colored conjugates and reactive reagents pre-spreaded at the corresponding regions.
Buffer	0.1 M Phosphate buffered saline (PBS) and 0.02% sodium azide.
Disposable pipettes	For adding specimens
Package insert	For operating instructions

MATERIALS REQUIRED BUT NOT PROVIDED

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

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in any area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The specimen dilution buffer contains sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of specimen dilution buffer or extracted samples, always flush with copious quantities of water to prevent azide buildup.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

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.**
- Cares 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 equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The *H. pylori* Antibody Rapid Test Device (Whole Blood/Serum/ Plasma) 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, lipemic, hemolysed, heat treated and contaminated specimens may cause erroneous results.

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 25µL) to the specimen well (S) of the device with the provided disposable pipette, then add 3 drops of buffer and start the timer.

   OR

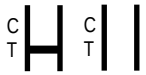
   Allow 1 drop of fingerstick whole blood specimen (approximately 25 µL) to fall into the center of the specimen well (S) of the device, then add 3 drops of buffer and start the timer.

   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 band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS

POSITIVE RESULT: 	Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).
NEGATIVE RESULT: 	Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).

INVALID RESULT: 	Control band fails to appear. Results from any test which has not produced a control band 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 contact your local distributor.

NOTE:

1. The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. But the substances level can not be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band 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. It confirms 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 THE TEST

1. The H. pylori Antibody Rapid Test Device (Whole Blood/Serum/Plasma) 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 bands.
2. 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.
3. 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.
4. 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.
5. Specimens from patients infected with C. jejuni may exhibit a low level of cross-reactivity in this test.

PERFORMANCE CHARACTERISTICS

Table: *H. pylori* Antibody Rapid Test vs. Biopsy/Histology/RUT

Relative Sensitivity:
93.2% (89.5%-95.9%)*
Relative Specificity:
97.2% (94.9%-98.6%)*
Overall Agreement:
95.5% (93.5%-97.0%)*
*95% Confidence Interval

		H. pylori Antibody Test		
		+	-	Total
Biopsy/ Histology/ RUT	+	246	18	264
	-	10	343	353
		256	361	617

LITERATURE REFERENCES

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GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer	Σ	Contains sufficient for <n> tests
	Do not reuse	EC REP	Authorized representative in the European Community
CE	CE marked according to IVD Medical Devices Directive 98/79/EC		

Liming Bio-Products Co., Ltd,
No. 12 Huayuan Road,Nanjing, Jiangsu, 210042
P.R. China.
Tel: (0086)25 85476723 Fax: (0086)25 85476387
E-mail: sales@limingbio.com
Website: www.limingbio.com
www.stddiagnostics.com
www.stidiagnostics.com

EC REP WellKang Ltd.(www.CE-marking.eu) Tel: +44(20)79934346
29 Harley St., London WIG 9QR,UK Fax: +44(20)76811874