

## One Step Rapid Test for H. Pylori Antibody

# MaxLINE H. pylori Antibody Rapid Test

### Whole Blood Test Protocol

#### ORDERING INFORMATION

Ref. No.	Pack Size
AVHPYWB - 10	10 tests
AVHPYWB - 20	20 tests
AVHPYWB - 25	25 tests
AVHPYWB - 30	30 tests
AVHPYWB - 50	50 tests

#### INTENDED USE:

The H. pylori Ab Rapid Test is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG, IgM, and IgA) anti- Helicobacter pylori (H. pylori) in human whole blood. It is intended to be used as a screening test and as an aid in the diagnosis of infection with H. pylori. Any reactive specimen with the H. pylori Ab Rapid Test Kit must be confirmed with alternative testing method(s) and clinical findings.

#### PRODUCT FEATURES

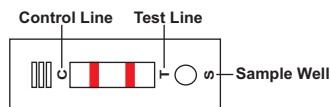
1. Lateral Flow Immuno Chromatography Assay.
2. Double Antigen Sandwich Principal.
3. detects IgG IgM Antibodies against H. pylori
4. Sensitivity :- 98.15%
5. Specificity :- 100%

#### INTRODUCTION:

Helicobacter pylori is associated with a variety of gastrointestinal diseases included non-ulcer dyspepsia, duodenal and gastric ulcer and active, chronic gastritis. The prevalence of H. pylori infection could exceed 90% in patients with signs and symptoms of gastrointestinal diseases. Recent studies indicate an association of H. pylori infection with stomach cancer. H. pylori colonizing in the gastrointestinal system elicits specific antibody responses which aids in the diagnosis of H. pylori infection and in monitoring the prognosis of the treatment of H. pylori related diseases. Antibiotics in combination with bismuth compounds have been shown to be effective in treating active H. pylori infection. Successful eradication of H. pylori is associated with clinical improvement in patients with gastrointestinal diseases providing a further evidence The H. pylori Combo Ab Rapid Test is a latest generation of chromatographic immunoassay which utilizes recombinant antigens to detect the antibodies to H. pylori in human whole blood. The test is user friendly, highly sensitive and specific.

#### PRINCIPLE:

The H. pylori Ab Rapid Test is a lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. The test cassette consists of: 1) a burgundy colored conjugate pad containing H. pylori antigens including Cag-A conjugated with colloid gold (H. pylori conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated H. pylori antigens, and the C band is pre-coated with goat anti-rabbit IgG.



When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. The antibodies: either the IgG, the IgM, or the IgA, to H. pylori if present in the specimen will bind to the H. pylori conjugates. The immunocomplex is then captured on the membrane by the pre-coated H. pylori antigens, forming a burgundy colored T band, indicating a H. pylori Ab positive test result.

Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-rabbit IgG/rabbit IgG-gold conjugate regardless the presence of any antibodies to H. pylori. Otherwise, the test result is invalid and the specimen must be retested with another device.

#### STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (4-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

#### KIT CONTAINS

Ref. No	Pack Size	Test Device	Buffer Vial	Product Insert
AVHPYWB-10	10 test	10 Nos.	1 No.	1 No.
AVHPYWB-20	20 test	20 Nos.	1 No.	1 No.
AVHPYWB-25	25 test	25 Nos.	1 No.	1 No.
AVHPYWB-30	30 test	30 Nos.	2 No.	1 No.
AVHPYWB-50	50 test	50 Nos.	3 No.	1 No.

#### MATERIALS

##### 1. Materials Provided

Each kit contains:

1. Test Device
2. Buffer
3. Sample Dropper
4. Product Insert

##### 2. Material Required But Not Provided

- Specimen collection containers
- Stop Watch

#### PRECAUTIONS:

1. For in vitro Diagnostic Use
2. This package insert must be read completely before performing the test. Failure to follow the insert giving inaccurate test results.
3. Do not open the sealed pouch, unless ready to conduct the assay.
4. Do not use expired devices.
5. Bring all reagents to room temperature (15°C-30°C) before use.
6. Do not use the components in any other type of test kit as a substitute for the components in this kit.
7. Do not use hemolyzed blood specimen for testing.
8. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
9. Users of this test should follow the US CDC Universal Precautions for prevention of handled.
10. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
11. Dispose of all specimens and materials used to perform the test as biohazardous waste.
12. Handle the Negative and Positive Control in the same manner as patient specimens.
13. The testing results should be read within 20 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 20 minutes may give erroneous results.
14. Do not perform the test in a room with strong air flow, ie. electric fan or strong air-conditioning.

#### SPECIMEN COLLECTION AND STORAGE:

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

##### Plasma

1. Collect blood specimen into a lavender, blue or green top collection tube (containing EDTA, citrate or heparin, respectively in Vacutainer® ) by veinpuncture.
2. Separate the plasma by centrifugation.
3. Carefully withdraw the plasma into new pre-labeled tube.

##### Serum

1. Collect blood specimen into a red top collection tube (containing no anticoagulants in Vacutainer®) by veinpuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.
4. Carefully withdraw the serum into a new pre-labeled tube.
5. Test specimens as soon as possible after collecting. Store specimens at 2°C to 8°C if not tested immediately.
6. Store specimens at 2°C to 8°C up to 5 days. The specimens should be frozen at -20°C for longer storage

##### Blood

Drops of whole blood can be obtained by either finger tip puncture or veinpuncture. Do not use any hemolyzed blood for testing. Whole blood specimens should be stored in refrigeration (2°C-8°C) if not testing immediately. The specimens must be testing within 24 hours of collection. Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

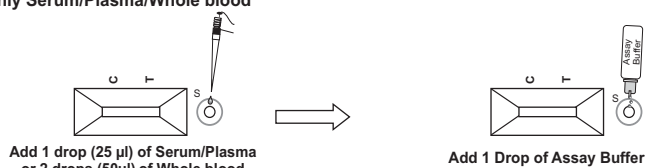
#### TEST PROCEDURE

1. Allow the test device, specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

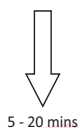
- Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
- Place the device on a clean and level surface.
- For **Whole Blood/Serum/Plasma** specimens: Hold the dropper vertically and transfer 1 drop (25µL) of serum/plasma or 2 drops (50 µL) of Whole blood into the specimen well (S) of the test device and then add 1 drop of Buffer (approximately 35 µL) and start the timer. See illustration below.

### INTERPRETATION OF RESULTS

Use Only Serum/Plasma/Whole blood



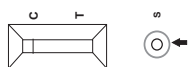
**\* Special Instruction \***  
25 µl Serum/Plasma or 50 µl Whole blood and 1 drop Assay Buffer



#### Interpretation of Result

##### Negative

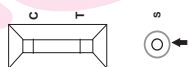
One bands appears in Window "C" Region



##### POSITIVE Result

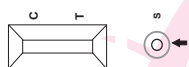
##### Positive

Two bands appears in Window "C" and "T" Region



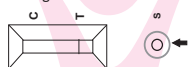
##### INVALID

No bands appears in Window Region. The Result is considered invalid



##### INVALID

The result should also be considered invalid if only test band appears and no control band appears in window region.



**Don't read results after 20 minutes. To avoid confusion, discard the test device after interpreting the result.**

### QUALITY CONTROL

A procedural control is included in the test. A color line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, 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.

### EXPECTED VALUES

The H. pylori Ab Rapid Test (Serum/Plasma/Whole blood) has been compared with a leading commercial H. pylori Ab test, demonstrating an overall accuracy greater than or equal to 98.15%.

### PERFORMANCE CHARACTERISTICS

#### Clinical Performance

A total of 200 specimens from the non- H. pylori patients and 75 specimens from the patients under anti-H. pylori treatment were tested by the H. pylori Ab Rapid Test. Comparison for all subjects is showed in the following table

	H. pylori Ab Rapid Test Kit		
H. pylori Patients	Positive	Negative	Total
Positive	65	10	75
Negative	18	182	200
Total	83	180	275

Relative Sensitivity:98.15%, Relative Specificity:100%, Overall Agreement:99.6%

### PRECISION

#### Intra-Assay

Within-run precision has been determined by testing 15 replicates of three specimens : a negative, a low positive and a high positive. The negative, low positive and high positive values were correctly identified 99% of the time.

Ver. : 04/08-25

### Inter-Assay

Between-run precision has been determined by testing 15 replicates on the same three specimens : a negative, a low positive and a high positive. Three different lots of the H pylori Rapid Test (Serum/Plasma/Whole blood) have been tested over a 3-month period using negative, low positive and high positive specimens. The specimens were correctly identified 99% of the time.

### INTERFERING SUBSTANCES

The following potentially interfering substances were added to H pylori IgG IgM negative and positive specimens.

Acetaminophen:	20 mg/dL	Caffeine:	20 mg/dL
Acetylsalicylic Acid:	20 mg/dL	Gentisic Acid:	20 mg/dL
Ascorbic Acid:	2g/dL	Albumin:	2 g/dL
Creatin:	200 mg/dL	Hemoglobin	1.1 mg/dL
Bilirubin:	1g/dL	Oxalic Acid:	600mg/dL

None of the substances at the concentration tested interfered in the assay.

### LIMITATIONS

- The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to H. pylori bacteria in serum or plasma from individual subjects. Failure to follow the procedure may give inaccurate results.
- The H. pylori IgG/IgM Rapid Test is limited to the qualitative detection of antibodies to H. pylori bacteria in human serum/plasma/whole blood. The intensity of the test band does not correlate with antibody titre of the specimen.
- A negative result for an individual subject indicates absence of detectable H. pylori bacteria antibodies. However, a negative test result does not preclude the possibility of exposure to or infection with H. pylori bacteria.

### DISCLAIMER:

The manufacturer has take every precaution to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the manufacturer and Distributor and the result may accordingly be affected by user error and/or environmental factors. A person who is the subject of the diagnosis should consult a clinical for further confirmation of the result.















### WARNING:

The manufacturer and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

### REFERENCE

- Anderson, L.P., Nielsen, H. (1993) Peptic ulcer: an infectious disease? Ann. Medg. 563 - 568.
- Evans, D.J., Evans, D.G., Graham, D.Y., Klein, P.O. (1989) A sensitive and specific serologic test for detection of Campylobacter pylori infection. Gastroenterology Th 1004 - 1008.
- Hunt, R.H., Mohamed, A.H. (1995) The current role of Helicobacter pylori: eradication in clinical practice. Scan. J. Gastroenterol. 30 suppl 208, 47 - 52.
- Lambert, J.R., Lin, S.K., Aranda-Michel, J. (1995) Helicobacter pylori. Scan. J. Gastroenterol. 30 suppl 208, 33 - 46.

### Symbols Used on Pack

	Catalogue Number		Warning/Caution
	Batch No.		In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Do Not Reuse		Contains sufficient no. of test



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