GENESIS

P221103 CE IVD

EZER™ *H. pylori* Antibody Rapid Test

Feb 2023, Ver. 02

INTENDED USE

The *EZER*™ *H. pylori* Antibody Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies to *H. pylori* in human Whole Blood/Serum/Plasma. It provides an aid in the diagnosis of infection with *H. pylor*i. It's an *in vitro* diagnostic test for professional use only.

BACKGROUND

H. pylori is implicated in the etiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcer, non-ulcer dyspepsia and active and chronic gastritis. *H. pylori* infection is found in more than 90% of duodenal ulcer patients and in around 75% of all peptic ulcer sufferers. *H. pylori* infection is also more common in gastric cancer patients. The risk of gastric cancer has been estimated to be six-fold higher in *H. pylori* infected populations than in uninfected populations. *H. pylori* infections occur in human populations throughout the world. In developed countries, about 50% of the population may have *H. pylori* infection by the age of 60 years, while only 10- 20% of adults in the third decade of life have it. Transmission is most probably by the fecal-oral or oral-oral route.

Both invasive and non-invasive methods are used to diagnose *H. pylori* infection in patients with symptoms of gastrointestinal disease. Invasive methods include culture of gastric biopsy samples, histologic examination of stained biopsy specimens, or direct detection of the urease activity in the biopsy (CLO test). These methods need to obtain a biopsy sample by endoscopy, which is expensive, and usually results discomfort and risk to the patient. Noninvasive techniques include urea breath tests and serological methods. Urea breath test requires expensive laboratory equipment and moderate radiation exposure. Serological tests are employed to detect antibodies as human immune response to *H. pylori*, for example the ELISA and the Western immunoblot.

The *H. pylori* Antibody Rapid Test detect antibodies to *H. pylori* infection in human Whole Blood/Serum/Plasma. It is a noninvasive method and does not use radioactive isotopes. The test is easy to perform and requires no specialized equipment. Visual interpretation provides an accurate qualitative result. It is a useful on-site aid in the diagnosis of *H. pylori* infection. Diagnosis of *H. pylori* infection by antibody immunoassay can reduce the number of patients requiring endoscopy.

PRINCIPLE

The *H. pylori* Antibody Rapid Test (Whole Blood/Serum/Plasma) is a qualitative lateral flow immunochromatographic assay for the detection of total antibodies to *H. pylori* in whole blood, serum or plasma specimen.

The test uses anti-human antibody (test line T) and goat anti-rabbit IgG (control line C) immobilized on a nitrocellulose strip. During testing, the specimen reacts with *H. pylori* antigen coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with anti-human antibody in T test line region, if the specimen contains antibodies to *H. pylori*, a colored line will appear in T test line region as a result of this.

Therefore, if the specimen does not contain *H. pylori* antibodies, no colored line will appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

CONTENTS

***EZER*™ *H. pylori* Antibody 40 test devices**

The test contains anti-human antibody as the capture reagent, *H. pylori* antigen as the detection reagent. A goat anti-rabbit IgG is employed in the control line system.

Sample buffer：1 vial

Plastic dropper：40 pcs

WARNINGS AND PRECAUTIONS

1. For in vitro Diagnostic Use.
2. Do not use kit components beyond the expiration date.
3. Pathogenic microorganisms may be present in clinical specimens. All specimen and the related contaminated items need to be handled, stored and disposed following "Standard Precautions" and institutional guidelines.
4. Wear protective clothing such as laboratory coats, masks, disposable gloves and eye protection when specimens are handled.
5. Ensure foil pouch containing test device is not damaged before opening for use.
6. The test plate should be used immediately after opening the packaging. When it absorbs moisture, the quality deteriorates and an accurate result cannot be obtained.
7. Please do not touch the sample drop and the judgment part of the test board directly by hand.
8. Do not reuse the device.
9. Use a clean, sterile pipette tip or dropper for each sample.
10. Please ensure that an appropriate quantity of samples

is used for testing. Too much or too little sample size may lead to deviation of results.

11. If the test is invalid, one should consider the possible improper handling, inaccurate operation procedure, or device quality. Repeat the test with a new device ensuring that the test procedure has been followed accurately.
12. Read the result at 15 min, or up to 30 min. Do not read the result longer than 30 min, because the result might be altered if the device is dry out.
13. All samples and used accessories should be treated as infectious and discarded according to local regulations.

STORAGE CONDITIONS

Test devices must be stored at 2~30°C. **DO NOT FREEZE.** Devices must be at ambient room temperature at time of testing.

SAMPLE COLLECTION AND PREPARATION

- Applicable samples：Whole Blood/Serum/Plasma.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolysis specimens.
- Testing should be performed immediately after the specimens have been collected. 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 7 days, for long term storage, serum/plasma 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 finger stick 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 local regulations covering the transportation of etiological agents.
- K2-EDTA, Sodium Heparin, Sodium Citrate and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

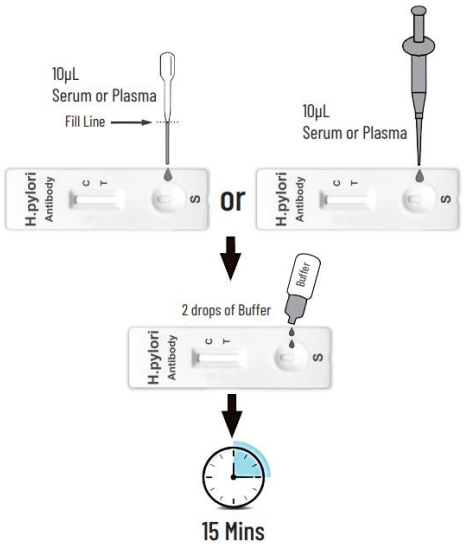
PROCEDURE

Allow the *EZER*™ *H. pylori* Antibody Rapid Test and collected samples to equilibrate to room temperature (15~30°C) prior to testing. Refer to testing procedures printed inside the kit.

1. Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed.
2. Open the foil pouch and take out the reagent plate. Once opened, test immediately. Write down the patient's name or number on the reagent plate. (One patient per reagent plate)
3. **For Serum or Plasma Specimen**：
   - To use a dropper：Hold the dropper vertically, draw the specimen to the fill line (approximately 10μL), and transfer the specimen to the specimen well (S), then add 2 drops of buffer (approximately 80μL), and start the timer.
   - To use a pipette: To transfer 10uL of specimen to the specimen well, then add 2 drops of buffer (approximately 80μL), and start the timer.

   See illustration below.

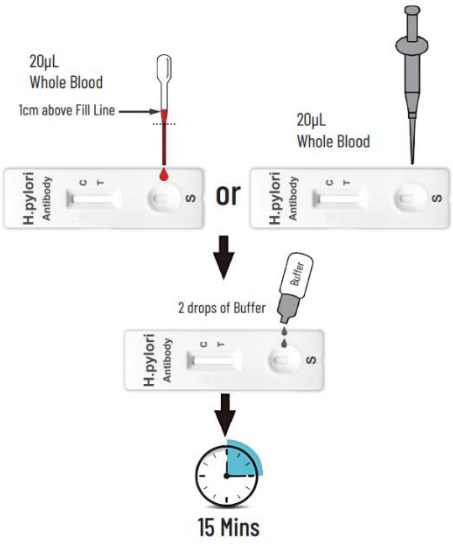
<u>Serum or Plasma Specimen</u>：



4. **For Whole Blood Specimen**：
   - To use a dropper: Hold the dropper vertically, draw the specimen about 1 cm above the fill line and transfer 1 full drop (approx. 20μL) of specimen to the sample well. Then add 2 drops of buffer (approximately 80μL) and start the timer.
   - To use a pipette: To transfer 20μL of whole blood to the specimen well, then add 2 drops of buffer (approximately 80μL), and start the timer

   See illustration below.

<u>Whole Blood Specimen</u>：

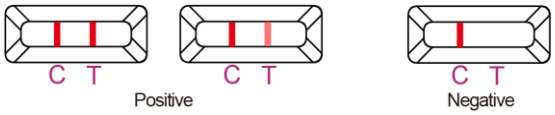


5. **Read the results after 15 minutes. If more than 30 minutes, please retest with another test card.**

Note: It is suggested not to use the buffer, beyond 6 months after opening the vial.

INTERPRETATION OF RESULTS

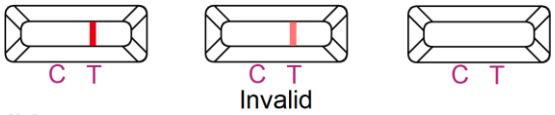
Allow the samples to react according to the procedure and read the red purple lines that appear in the reading area.



Positive:
The colored line in the control line region (C) appears and a colored line appears in test line region (T). The result is positive for *H. pylori* specific antibodies.

※NOTE: The intensity of the color in the test line region (T) will vary depending on the concentration of *H. pylori* antibodies in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

Negative Result:
The colored line in the control line region (C) appears. No line appears in test line region (T).



Invalid:
Control band fails to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

PRECAUTIONS FOR ASSESSMENT

1. Assessment must be conducted exactly 15 minutes after starting the reaction. Given the nature of the measurement (immunochromatography), the reaction and color development may slightly continue and progress even after 15 minutes.
2. The color tone of the line may vary depending on the color tone and specimen properties. However, the test result is valid as long as a red line is present. Occasionally, broken lines may appear, but the test result is valid as long as a red line is present.
3. If the line is not red at all (e.g. black), the test result is invalid and another test should be performed.
4. If the specimen is dark-colored, it may stain the membrane and affect the assessment.
5. A highly viscous specimen may affect sample migration and/or the reaction, resulting in weak coloration, delayed or no formation of the line, or a nonspecific reaction because of specimen retention.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is 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.

PERFORMANCE CHARACTERISTICS

Sensitivity and specificity

The *EZER*™ *H. pylori* Antibody Rapid Test was compared with a leading commercial PCR; the results show that *EZER*™ *H. pylori* Antibody Rapid Test has a high sensitivity and specificity.

Result :		PCR		
		+	−	Total
The *EZER*™ *H. pylori* Antibody	+	142	4	146
	−	3	147	150
	Total	145	151	296

Positive Percent Agreement: 97.9%
Negative Percent Agreement: 97.4%
Overall Percent Agreement: 97.6%

Cross-reactivity evaluation

The *EZER*™ *H. pylori* Antibody Rapid Test has been tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-Syphilis, anti-HIV and anti-HCV positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have been tested using the *EZER*™ *H. pylori* Antibody Rapid Test and no interference was observed.
Triglyceride: 50 mg/dL Ascorbic Acid: 20mg/dL
Hemoglobin 1000mg/dL Bilirubin: 60mg/dL
Total cholesterol: 6mmol/L

LIMITATIONS OF THE PROCEDURE

1. The *EZER*™ *H. pylori* Antibody Rapid Test is for *in vitro* diagnostic use only. This test should be used for detection of antibodies to *H. pylori* in whole blood, serum or plasma specimens.
2. Neither the quantitative value nor the rate of increase in the concentration of antibodies to *H. pylori* can be determined by this qualitative test.
3. The *H. pylori* Antibody Rapid Test (Whole blood/Serum/Plasma) will only indicate the presence of antibodies to *H. pylori* in the specimen and should not be used as the sole criteria for the diagnosis of *H. pylori* infections.
4. A negative result can occur if the quantity of *H. pylori*

antibodies present in the specimen is below the detection limits of the assay.

5. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
6. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
7. The results obtained with this test should be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES

1. O'Connor, JH., Helicobacter pylori and gastric cancer: a review and hypothesis. Eur. JGastro.Hepa.1992:6: 103-109.
2. Mcguigan JE., Peptic ulcer and gastritis. In Harrison's Principles of Internal Medicine12th Edition,1988, Chapter 238,1229-1248.
3. Cover TL. and Blaser MJ., Helicobacter pylori: A Bacterial Cause of Gastritis, PepticUlcer Disease,and Gastric Cancer, ASM News,1995: 61: 21-26.
4. Podolsky I, Lee E, Cohen R, Peterson WL. Prevalence of' C. pylori in healthy subjects andpatients with peptic diseases. Gastroenteroloty 1989: 96: Suppl: A394. abstract.
5. Kist M., Immunology of Helicobacter pylori. In Helicobacter pylori in peptic ulcerationand gastritis, edited by Marshall B. McCallum RW., and Guerrant RL, 1991, Chapter 8.92-110.

Index of Symbols

	Attention, see instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
	Store between 2~30℃	LOT	Lot Number	REF	Catalog #

EC REP **CMC Medical Devices & Drugs S.L.**
C/ Horacio Lengo no 18, CP 29006,
Málaga, Spain

HANGZHOU GENESIS BIODETECTION AND BIOCONTROL CO., LTD.
ADD：NO.139, St.10th (East), Hangzhou Economic & Technological Development Zone. Hangzhou, Zhejiang Province, China, 310018
TEL： +86-571-87818163
FAX： +86-571-8782-4695
Web：www.genesis-ivd.com