GENESIS

CE IVD

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P221007 EZER™ H. pylori Antigen Rapid Test

This kit is designed for testing freshly collected Fecal Specimen.

INTENDED USE

The EZER™ H. pylori Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of *Helicobacter pylori* (*H. pylori*) antigens in human feces specimens to aid in the diagnosis of *H. pylori* infection.

Any interpretation or use of this preliminary test result must also rely on other clinical findings as well as on the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

BACKGROUND

H. pylori is a spiral-shaped gram negative bacteria, the most common infectious microorganism found in humans, and infects approximately 50% of the world's populations.[1] *H. pylori* can be transmitted through the ingestion of food or water that is tainted with fecal matter. *H. pylori* infection is a risk factor for a variety of gastrointestinal diseases including non-ulcer dyspepsia, duodenal and gastric ulcers and active, chronic gastritis and stomach cancer, and MALT (mucous-associated lymphoid tissue) lymphoma[2-9].

H. pylori infection can be diagnosed using invasive or noninvasive methods.

H. pylori infection is currently detected by invasive testing methods based on endoscopy and biopsy (i.e. histology, culture) or non-invasive testing methods such as Urea Breath Test (UBT), serologic antibody test and stool antigen test.[10] Another noninvasive method, serology testing, is not recommended for evaluating treatment effectiveness as it is unable to distinguish between active infection and previous exposure to *H. pylori*.[11]

The EZER™ H. pylori Antigen Rapid Test detects *H. pylori* antigen present in the fecal specimen.

PRINCIPLE

The EZER™ H. pylori Antigen Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of *H. pylori* antigens in human feces specimens, providing results in 15 minutes. The test utilizes antibodies specific for *H. pylori* antigens to selectively detect *H. pylori* antigens in human feces specimens.

The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against *H. pylori*; the reaction membrane contains the secondary antibodies for *H. pylori* and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane. The whole strip is fixed inside a plastic device. When the sample is added into the sample window, conjugates dried in the reagent pad are solubilized and migrate along with the sample. If *H. pylori* presents in the sample, a complex formed between the anti-*H. pylori* conjugate and the *H. pylori* will be captured by the specific anti-*H. pylori* monoclonal coated on the Test Region (T). Results appear at 15 minutes in the form of a red line that develops on the membrane.

To serve as a procedural control, a red line will always appear in the control region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

CONTENTS

H. pylori antigen test device (20), Stool collection tube (20), Package insert (1).

STORAGE CONDITIONS

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

Warnings and Precautions

1. For *in vitro* Diagnostic Use
2. 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.
3. Use the stool collection tube supplied in the kit for collection fecal specimen.
4. Proper specimen collection, storage and transport are critical to the performance of this test.
5. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated.
6. Do not use kit components beyond the expiration date.
7. Apply universal precaution when performing the test.
8. 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.
9. Please do not touch the sample drop and the judgment part of the test board directly by hand.
10. Do not reuse the device.
11. Do not scoop stool sample as this may lead to excess fecal specimen that tends to clog the sample pad and interfere with sample migration.
12. 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.

13. Assessment must be conducted exactly 15 minutes after starting the reaction. Given the nature of the measurement, the reaction and color development may slightly continue and progress even after 15 minutes. Disregard test results beyond specified time (30 min).
14. 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.
15. If the line is not red at all (e.g. black), the test result is invalid and another test should be performed.
16. 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.

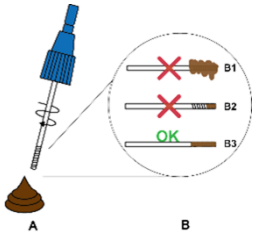
SPECIMEN COLLECTION AND PREPARATION

DOs and DON'Ts of Sample Collection

- Stool specimens should be collected in a clean container that do not contain media, preservatives or detergents as any of these additives may interfere the results.
- The feces samples need to be performed as soon as possible after collection. If not, the specimen collected may be stored for one week at 2-8°C or stored a longer period at -20°C.
- Do test sample immediately.
- Use only stool collection tube provided with the kit.
- This kit is not intended for testing liquid samples

Prepare test samples with stool collection tube (with extraction buffer) for immediate testing after collection. If immediate testing is not possible, collected samples can be held refrigerated (2~8°C) for up to 48 hours prior to testing. Inadequate sample collection or improper sample handling may yield a false-negative result.

1. Label information of studied specimens on the blue color stool collection tube.
2. Specimen collection
   (1) Open the stool collection device by unscrewing the top and use the collection stick to randomly pierce in 2-5 different sites, to collect the feces specimen 50mg (A), too more (B1) or too less (B2) are both not available. Put the "collection stick" back to the stool collection tube.



   (2) For the liquid or semi-liquid specimen, use pipette (not provide) to transfer 80μL specimen into stool collection tube containing the extraction buffer.
3. Tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen.

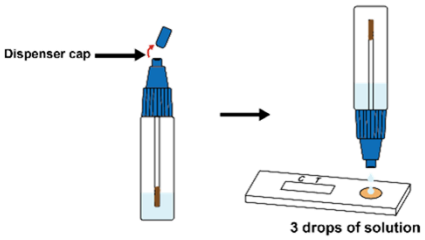
Note： All the specimen should be mixed into solution.

4. Do not leave specimen at room temperature for prolonged periods. Specimens can temporarily store at 2-8℃ for 7 days. For longer storage, the extracted specimen may be frozen at -20°C. Avoid multiple freeze-thaw cycles.

PROCEDURE

Reagents, specimens and devices must be at room temperature (15–30 °C) for testing.

1. Bring the specimen and test components to room temperature if refrigerated or frozen.
2. Once the specimen is thawed, mix well prior to performing the assay.
3. Remove a test cassette from its foil pouch and place it on a flat surface.
4. Shake the stool collection device vigorously to ensure a homogenous liquid suspension.
5. Twist off (or cut) the blue tip on the top of the sample preparation tube and dispense 3 drops of the extracted specimen (approximately 80μL) to the sample well of the cassette.

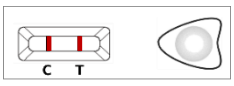


6. Do not overload the solution.
7. Avoid trapping air bubbles in the sample well
8. Read results at 15 minutes and disregard after 30 minutes. A positive result may be visible at 3 minutes. However, the complete reaction time of 15 minutes is required to confirm a negative result.

INTERPRETATION OF RESULTS

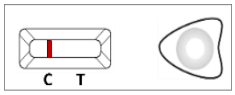
Allow the samples to react according to the procedure and read the red lines that appear in the reading area.

Positive Result



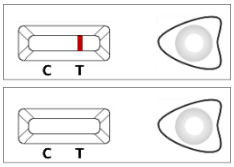
Two red lines appear. One red line appears in the control region (C), and one red line in the test region (T). The shade of color may vary，but it should be considered positive whenever there is even a faint line. A positive result indicates that the *H. pylori* antigen is in the stool specimen.

Negative Result



Only one red line appears in the control region (C), and no line in the test region (T).
The negative result indicates that the *H. pylori* antigen is absent or below the level of detection.

Invalid Result



No red line appears in the control region (C). The test is invalid even if there is a line on test region (T). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal control

Each EZER™ H. pylori antigen rapid test device contains internal/procedural controls. The appearance of a control line at the Control "C" position validates the proper reagent function and assures that the correct test procedure was followed.

PERFORMANCE CHARACTERISTICS

Minimum detection limit

The minimum detection limit for the EZER™ H. pylori Antigen Rapid Test is 1.3×10^5 CFU/ml for *H. pylori* strain.

Clinical study

The clinical evaluations for EZER™ H. pylori Antigen Rapid Test was compared to a immunochromatographic assay method (Wondfo *H. Pylori* Antigen, CFDA-cleared) at three clinical site in China a total of 1261 patient

		Wondfo H. Pylori Antigen		
		+	−	Total
EZER™ H. Pylori Antigen	+	419	13	432
	−	9	820	829
	Total	428	833	1261

Relative Sensitivity：97.90% (95%CI*: 96.05%～99.03%)
Relative Specificity：98.44% (95%CI*: 97.35%～99.17%)
Accuracy：98.26% (95%CI*: 97.37%～98.90%)

Cross-reactivity evaluation

The cross reactivity of the EZER™ H. pylori Antigen Rapid Test was assessed by testing the following microorganisms.

1. Bacteria and Yeast
   No cross reactivity with following bacteria when the bacterial concentration is 1×10^8 cfu/ml：
   Acinetobacter calcoaceticus, Aeromonas hydrophila, Bacteroides fragilis,Campylobacter jejuni, Candida albicans, Citrobacter freundii, Clostridium difficile, Clostridium perfringens, Enterococcus faecalis, Escherichia coli, Haemophilus influenza, Klebsiella pneumoniae, Listeria innocua,Moraxella catarrhalis, Proteus vulgaris, Pseudomonas aeruginosa, Salmonella Paratyphi A, Salmonella Paratyphi B, Salmonella Paratyphi C, Salmonella typhi, Serratia marcescens18, Shigella flexneri, Shigella sonnei, Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus Group A, Streptococcus Group B, Streptococcus Group C, Streptococcus Group F, Streptococcus Group G, Streptococcus pneumoniae, Vibrio parahaemolyticus, Yersinia enterocolitica
2. Virus
   No cross reactivity with following virus when the virus concentration is 1×10^7 $TCID_{50}$/ml：
   Adenovirus type 41, Rotavirus,

Endogenous/Exogenous Interference Substances

Not disturbed by the color and consistence of fecal specimen.

Not disturbed when containing the hemoglobin concentration is not higher than 177g/L and bilirubin concentration is not higher than 241.3μmol/L.

The following substances were found to have no effect on results when present in stool at the concentrations indicated.

Substance	Concentration
Aspirin	3 mg/ml
Barium sulfate	5%
Metronidazole	0.25 mg/ml
Mylanta	5% (w/v)
Omeprazole	5 mg/ml
Pepto-Bismol®	5% (w/v)
Tagamet® Antacid	5 mg/mL
Tums® Antacid	5 mg/mL

LIMITATIONS OF THE PROCEDURE

1. This kit is a qualitative test and cannot determine the amount of antigen in the sample.
2. A negative test result may occur if the level of antigen in a stool sample is below the detection limit of the test. Test results must be evaluated in conjunction with other clinical data available to the physician.
3. 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 preclude the possibility of *H. pylori* infection.
4. The EZER™ H. pylori Ag Rapid Test is limited to the qualitative detection of *H. pylori* antigen in human fecal specimen. The intensity of the test line does not have a linear correlation with the antigen titer in the specimen.
5. Failure to follow the procedure, particularly the Specimen Collection and Handling procedure, may lead to inaccurate results.
6. A negative test result does not rule out the possibility of *H. pylori* infection for not all *H. pylori* strains can be detected by the kit.

AVAILABILITY

Product	Cat. No.	Contents
EZER™ H. pylori Antigen Rapid Test	P221007	20 Tests

REFERENCES

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10. Shimoyama T, Kato T, Kodama M, et al. Applicability of a monoclonal antibody-based stool antigen test to evaluate the results of Helicobacter pylori eradication therapy. Jpn J Infect Dis 2009. 62(3):225-7.
11. Chey WD. American College of Gastroenterology guideline on the management of Helicobacter pylori infection. Am J Gastroenterol. 2007, 102, 1808-1825.

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 **Lotus NL B.V.**
Koningin Julianaplein 10, le Verd, 2595AA,
The Hague, Netherlands.
e-mail：peter@lotusnl.com

Hangzhou Genesis
Biodetection and Biocontrol Co., Ltd.
ADD：No.139, 10th Street (East) ,Hangzhou
Economic & Technological Development Zone.
Hangzhou, China, 310018
TEL：+86-571-87818163
FAX：+86-571-8782-4695
Web：https://www.genesis-ivd.com