HP (Helicobacter Pylori) Antigen Detection Kit

(Fluorescence Immunochromatography)

User Manual

（For Medical Professional Use Only）

1.Product Name

HP (Helicobacter Pylori) Antigen Detection Kit (Fluorescence Immunochromatography)

2.Package Specification

20 T/box

3.Intended Use

This kit is used to qualitatively detect HP (Helicobacter Pylori) antigen in fecal samples in vitro.

4.Summary

Helicobacter pylori (HP) is a spiral-shaped, Gram-negative bacterium typically found in the mucous layer of the stomach or attached to the upper layer of the stomach that infects the gastric mucosa. It causes more than 90 percent of duodenal ulcers and nearly 80 percent of stomach ulcers. The importance of HP antigen testing has increased with the establishment of a strong association between the presence of this bacterium and the diagnosis of gastrointestinal (stomach and duodenum) diseases such as gastritis, gastric ulcers, and gastric cancer.

5.Test Principle

HP (Helicobacter Pylori) Antigen Detection Kit (Fluorescence Immunochromatography) adopts double antibody sandwich fluorescence immunochromatography. The NC membrane detection line (line T) on the detection card is coated with HP antibody, and the quality control line (line C) is coated with anti-DNP antibody. During the test, HP antigen in the sample combine with HP antibody labeled by fluorescent microspheres to form a reaction complex [fluorescent microsphere -(HP-Ab)-(HP-Ag)]. The reaction complex moves forward along the nitrocellulose membrane under the action of chromatography and moves to the detection line (line T). The reaction complex is captured by the antibody coated by the detection line to form the final reaction complex. The fluorescent microsphere emits fluorescence signal under excitation of excitation, and the concentration of HP antigen in the sample is positively correlated with the fluorescence signal. The concentration of HP antigen in the sample was calculated by fluorescence immunoassay according to the relative fluorescence signal intensity of the sample.

6.Components

This test kit consist of :

① Individually Packaged Test Cassette

a. One kit device

b. One desiccant

② Sample buffer: 4 mL/bottle/test

③ ID Card

④ Quick Reference Instructions

7.Materials Required but not Provided

(1)Timer or watch

(2)Fluorescent Immunoanalyzer

(Model type: GTF2600, GTF3000B. Manufactured for International Biomedical Supplies INC.)

8.Storage and Expiration Date

It is stored at 2~30℃, and its validity period is 24 months. After the aluminum foil bag is opened, the test card should be used within 60 minutes. See the product label for the production date and expiration date.

9.Specimen Requirements

1. The samples tested are human feces, which shall be collected and transported in accordance with standard laboratory procedures.

2. Samples should be stored at 2~8℃, and sample detection should be carried out within 24 hours after sample collection as far as possible.

3. If longer storage time is required, it can be stored at -15℃ for 9 days to avoid repeated freeze-thaw.

4. Samples must be at room temperature before testing, and frozen samples must be thoroughly thawed and restored to room temperature before use.

5. Sample treatment: Collect the fecal sample with the fecal collection tube, and mix with the diluent in the collection tube for use. Diluted stool samples should be tested as soon as possible within 1 hour.

10.Testing Procedures

Before using the reagent, please read the instructions of the kit and the immunofluorescence detector carefully, and operate in strict accordance with the instructions to ensure the accuracy of the results.

- Machine operate

1. Before the experiment, take out the samples and test reagents to be tested from the storage conditions and balance them to room temperature.

2. Take out the kit ID card and store the kit data in the fluorescence immunoassay analyzer.

3. Put the test card in the card warehouse.

4. Open the aluminum foil bag, take out the test card, and place it horizontally on the test bench.

5. Unscrew the top of the collection tube and remove the applicator stick.Randomly pierce the stool specimen in at least five different sites.Replace the stick in the tube and tighten securely.

6. Shake the specimen collection tube vigorously to mix the specimen and the dilution buffer. Leave the tube alone for 2 minutes.

7. The specimen collection tube was shaken, placed on the test tube rack, and tested by machine.

8. Select the sample type on the machine, establish the test task, and give the results after 15 min.

- Manual operate

1. Before the experiment, take out the samples and test reagents to be tested from the storage conditions and balance them to room temperature.

2. Take out the kit ID card and store the kit data in the fluorescence immunoassay analyzer.

3. Open the aluminum foil bag, take out the test card, and place it horizontally on the test bench.

4. Unscrew the top of the collection tube and remove the applicator stick.Randomly pierce the stool specimen in at least five different sites.Replace the stick in the tube and tighten securely.

5.Shake the specimen collection tube vigorously to mix the specimen and the dilution buffer. Leave the tube alone for 2 minutes.

6. Take 75 μ L of liquid in the stool collection tube onto the reagent card;

7. React at room temperature for 15 minutes, use fluorescence immunoassay analyzer to test, read or print the test results.

11.Expected Value

Critical value: 50 ng/mL, ≥50 ng/mL is positive.

12.Interpretation of Test Result

1. Use fluorescent immunoanalyzer to analyze the test card and issue quantitative test results. Professional personnel are responsible for the review and analysis of test results, which are usually considered normal within the reference range and are influenced by age, sex, diet and region.

2. The test results of this reagent are for clinical reference only, and the clinical diagnosis and treatment of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests and treatment response.

13.Limitation of Test Method

1. This kit is applicable to the detection of human fecal samples. Detection with other samples or solutions, errors in operation, and interfering substances in samples may lead to incorrect results.

2. The test results of this kit can only be used as an auxiliary reference for clinical diagnosis. If the test results are inconsistent with the clinical evaluation, further examination is required.

14.Warnings and Precautions For *in Vitro* Diagnostic Use

1. This kit is only used for in vitro diagnosis. It is prohibited to use in vivo in any form. Do not use expired products.

2. This kit should complete the test as soon as possible within 15 minutes after adding samples, otherwise the accuracy of the test results will be affected.

3. The collected, transported and discarded test samples, used reagents and other wastes shall be disposed according to the medical waste regulations.

4. Each detection card is disposable. Do not reuse it.

5. The operation shall be carried out in strict accordance with the instructions. The components of the kit with different batch numbers cannot be mixed.

6. This kit is designed to qualitatively detect the content of H. pylori antigen in fecal samples. The test results of the reagent must be analyzed in combination with the clinical information of the patient.

7. Do not insert the detection card whose surface is wetted by blood or other liquid into the instrument, otherwise it will pollute or damage the instrument.

8. Vibration and electromagnetic environment shall be avoided when testing cards and instruments. In normal use, the vibration of the instrument itself is a normal phenomenon.

15.Reference

1.Bruce E. Dunn, Hartley Cohen & Martin J. Blaser. Helicobacter pylori. Clin. Microbiol. Rev. 10(4), 720-741, Oct. (1997).

2.Martin J. Blaser. Helicobacter pylori and gastric diseases. BMJ;316:1507-1510(1998).

3.John L. Telford, Antonello Covacci, Rino Rappuoli & Paolo Ghiara. Immunobiology of Helicobacter pylori infections. Current Opinion in Immunology,9;498-503(1997) .