V1.0

fluorecare® **Hp-Ag** CE

PRODUCT NAME

Common Name: Helicobacter pylori Antigen (Hp-Ag) Diagnostic Kit (Immunochromatographic Assay)
Product code: MF-80

PACKING

20 Tests/box、25 Tests/box

INTENDED USE

This kit is used for in vitro qualitative detection of H.pylori antigen in human fecal sample.
H.pylori is a Gram-negative Helicobacter parasitized in human gastric mucosa, and studies have shown that H.pylori can damage gastric mucosal epithelial cells and that its increased value-added nuclear cell antigen is found in gastric mucosal epithelial cells of H.pylori-positive patients, whereas hyperproliferation of gastric mucosal epithelial cells is an important pathological change for carcinogenesis. H.pylori is the main pathogenic bacteria of chronic gastritis and peptic ulcer, and is closely related to the development of gastric cancer and gastric mucosa associated lymphoid tissue lymphoma. H.pylori is mainly transmitted by mouth to mouth and feces to mouth and mostly clusters in households, so early confirmation of H.pylori infection is beneficial for early disease diagnosis, treatment as well as prevention.

PRINCIPLE

This kit, based on the principle of immunochromatography assay, is used to detect the concentration of H.pylori antigen in human faeces by double antibody sandwich method. After adding the sample solution, the H.pylori antigen in the sample will react with the mouse-anti-H.pylori monoclonal antibody labeled with fluorescently-labeled on the bonding pad, and the antigen-antibody complex is formed. Due to chromatography, the solution diffuses along the nitrocelluloses membrane. In the test line region, the antigen-antibody complex is captured by another mouse anti-H.pylori monoclonal antibody on the nitrocellulose membrane, and present the fluorescent band. In the quality control line region, the fluorescently-labeled mouse-anti-rabbit IgG antibody is captured by rabbit IgG antibody on the nitrocellulose membrane, and present the fluorescent band.The fluorescence intensity of test line will be analyzed by the analyzer, the H.pylori antigen concentration will be calculated by the preset calibration curve, and the result will be displayed with the unit of S/CO.

MAJOR COMPONENTS

Components	Quantity	Quantity	Major Components
Test card	20 Cassettes	25 Cassettes	Each card is mainly composed of a plastic shell and a strip, the main part of the test strip is coated with the mouse-anti-H.pylori monoclonal antibody and the rabbit IgG antibody. The bonding pad is covered with the another fluorescently-labeled mouse-anti-H.pylori monoclonal antibody and the fluorescently-labeled mouse-anti-rabbit IgG antibody, and other component include the glass fiber and bibulous paper.
Sample collection tube	20 tubes	25 tubes	/
Diluent	2 tubes	3 tubes	Normal saline solution. 11mL per tube.
ID chip	1 Piece	1 Piece	Curve files of corresponding batch product.

Note: Instruments are needed but not supplied: Timer, thermometer, hygrometer, pipette and matched tubes.

STORAGE CONDITIONS AND EXPIRY DATE

The test card is stable for 18 months (while sealed in an aluminium foil pouch) if stored at 2-30℃. Keep away from sunlight. Once the test card pouch is opened, the test should be performed within 1 hour.

APPLIED INSTRUMENT

MF-T1000 Dry-type Immunofluorescence Quantitative Analyzer by **Shenzhen Microprofit Biotech Co., Ltd.**

REQUIREMENTS OF SPECIMENS

1. Sample collection: Take clean container to collect human fecal sample.
2. Sample preservation: If the fecal sample cannot be pretreated immediately, the sample should be stored at 2℃~8℃ (the sample should be pretreated within 3 days and the test completed); If the sample needs to be stored for a long time, it should be stored at -20℃ or lower temperature.
3. Sample pretreatment
   ①Open the sample collection tube and take out the sampling stick.
   ②Put a sampling stick into the fecal sample about 3~4 times at different sites (about 5~10mg) and add 1 mL diluent to the sample collection tube.
   ③Return the fecal sampling stick into the sample collection tube.
   ④Tighten the cap and shake the sample collection tube repeatedly until the sample on the stick is dissolved.

Note: The fecal samples stored at low temperature should be returned to room temperature before pretreatment. The samples should be tested immediately after pretreatment. If the samples can not be tested in time, the samples should be stored at 2-8 ℃ (the samples should be tested within 3 days). Do not use samples that have been stored for a long time, with bacteria, mildew or repeated freezing and thawing to avoid non-specific reaction caused by sample contamination, bacteria and mildew. The kit is not suitable for fecal sample of diarrhea patients.

TEST SETUP

1. When stored at low temperature, the kit should be restored to room temperature (15-30℃).
2. Turn on the instrument according to the instructions.
3. Check that the ID chip is consistent with the kit lot number and do not touch the insert end of the ID chip when inserting it.
4. Tear open the outer package, take out the test card and put it on the horizontal table. The test card should be used within 1 hour.
5. Drop 2 drops (about 70μL) of the mixture vertically and slowly into the sample well of the test card.
6. Keep the test card at room temperature 15 minutes for chromatographic reaction, and then insert it into test card holder of analyzer and start to test according to the analyzer instruction manual. Few seconds later, the result will be automatically displayed on the screen. The result can be kept and printed out as well.

Note: The experiment should be done at 15-30℃.

NTERPRETATION OF RESULTS

The reference value range of Hp-Ag kit is S/CO<1.00.
1. Positive: If the result is S/CO ≥ 1.00, show that for positive result.
2. Negative: If the result is S/CO < 1.00, show that for Negative result.

LIMITATION OF METHODOLOGY

1. This kit only used to detect Helicobacter pylori antigen in human fecal sample. And the kit can not be used as a quantitative kit.
2. The test results of this kit are only for clinical reference. The clinical diagnosis and treatment of patients should be considered in combination with their symptoms, signs, medical history, other laboratory tests and treatment

reactions.

INDEX OF CHARACTERISTICS

Use the company internal references for evaluation test, multiple indicators of the performance of the kit meet the standards. Specific performance indicators are as follows:

1. Sensitivity

The sensitive references provided by the manufacturer are tested for the sample, and the results should meet the requirements.

2. Specificity

The test results should be negative with the specific references provided by the manufacturer.

3. Within-run Repeatability

Take one lot number kit to test the repeated references provided by the manufacturer, the results should be positive, and the coefficient of variation of the S/CO value should be≤15%.

4. Between-run Repeatability

Take three different lot numbers kit to test the repeated references provided by the manufacturer, the results should be positive, and the S/CO value coefficient of variation should be≤15%.

ATTENTION

1. The kit is only used for *in vitro* diagnosis; it cannot be used repeatedly.
2. Kits should be treated as infectious materials.
3. All specimens, reagents and potential contaminants should be disinfected and treated in accordance with local regulations.
4. Please read the instructions of the kit and the instrument before the operation.
5. Different batches of reagent components cannot be mixed. Each batch of reagents has the corresponding parameters which must be updated. Otherwise, the new batch of products will not be identified by the instrument.

INTERPRETATION OF ICONS

	Do not re-use	30℃ 2℃	Temperature limit
IVD	*In vitro* diagnostic medical device		Consult instructions for use
Σ	Contains sufficient for *<n>* tests		Keep dry
	Keep away from sunlight	EC REP	Authorized representative in the European Community
	Manufacturer		Caution
REF	Catalogue number	CE	CE marking
	Date of manufacture	LOT	Batch code
	Use-by date		

REFERENCE

[1] Zhu L, Xu m, Zhang y, et al. Effect of different genotypes of Helicobacter pylori on causing immune damage in human gastric mucosal epithelial cells [J]. International Journal of digestive diseases, 2016,36 (1): 63-65DOI:10.3969/j.issn.1673-534X.2016.01.016.

[2] BYUN E, PARK B, LIM J W. et al. Activation of NF-kB and AP-1 mediates hyperproliferation by inducing B-catenin and c-Mve in Helicobacter pylori-infected gastric epithelial cells [J]. Yonsei Med J,2016. 57(3).647-651. DOI. 10.3349/mi. 2016.57.3.647.

[3] Helicobacter pylori and peptic ulcer study group, division of Gastroenterology, Chinese Medical Association, national H. pylori research collaborative group, Wenzhong Liu, et al. Fifth national consensus report on the management of H. pylori infection [J]. Chinese Journal of practical internal medicine, 2017,37 (6): 509-524DOI:10.19538/j.nk2017060110.

GENERAL INFORMATION

Shenzhen Microprofit Biotech Co., Ltd.

Rm. 405, 406, Zone B /4F, Rm. 205, 206-1, 207, West Side of Zone B/ 2F, Haowei Building, No. 8 Langshan 2nd Road, Songpingshan, Songpingshan Community, Xili Street, Nanshan District, Shenzhen, P.R. China

EC REP **MedNet EC-REP GmbH**

Borkstrasse 10 · 48163 Muenster · Germany

Zip Code: 518057

Tel: +86-755-61688835

Fax: +86-755-61688111

Website: www.microprofit-bio.com

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