

INTENDED USE

The Finicare™ H.pylori Ag Test along with Finicare™ FIA Meters (Model No.: FS-113/FS-114/FS-205) is a fluorescence immunoassay used for qualitative determination of H.pylori Ag in human feces. The test is used as an aid for the diagnosis of H. pylori infection.

For *in vitro* diagnostic use only. For professional use only.

SUMMARY

Helicobacter pylori (H.pylori) is a gram-negative, helix-shaped, bacterium usually found in the human stomach. It is the causative agent of chronic gastritis or inflammation of the stomach lining, duodenal and stomach ulcers, and is associated with an increased risk of stomach cancer. More than 50% of the world's population harbor H. pylori in their upper gastrointestinal tract. Individuals infected with H. pylori have a 10 to 20% lifetime risk of developing peptic ulcers and a 1 to 2% risk of acquiring stomach cancer.

PRINCIPLE

The Finicare™ H.pylori Ag Test is based on fluorescence immunoassay technology, specifically the sandwich immunodetection method. Add the specimen to extraction buffer and mix well. When the sample mixture is added into the sample well of the Test Cartridge, the fluorescence-labeled detector antibody on the conjugate pad will bind to antigen in specimen and form immune complexes. As the sample mixture migrates on the nitrocellulose membrane of test strip by capillary action, the complexes of detector antibody and antigen are captured to the other antibody that has been immobilized on membrane. Thus the more antigen is in specimen, the more complexes are accumulated on membrane.

Signal intensity of detector antibodies reflect the amount of antigens. The default results unit of Finicare™ H.pylori Ag Test is displayed as cut-off index (COI) from Finicare™ FIA Meters.

PRECAUTIONS

1. This kit is *in vitro* diagnostic use only. Do not swallow.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date printed on the package.
4. Do not use Test Cartridge if its Lot No. does not match with Lot No. of ID Chip that is inserted into the Finicare™ FIA Meters.
5. The desiccant is for storage purposes only, is not used in the test procedures.
6. The Finicare™ H.pylori Ag Test is only operational in the Finicare™ FIA Meters. The tests should be applied by well-trained healthcare

professionals, and conducted in laboratories, GP offices, clinics, pharmacy etc.

7. The Test Cartridge should remain in its original sealed pouch until ready to use. Do not use the Test Cartridge if the pouch is punctured or not well sealed. Discard after single use.

8. There is a blue line on the test membrane, it will disappear after sample adding. This indicates that Test Cartridge has been used. Do not reuse the Test Cartridge.

9. Do not use damaged or stained materials provided in the test kit.

10. The test kit and instrument should be used away from vibration and magnetic field. During normal usage, the instrument may introduce minute vibration, which should be regarded normal.

11. Test Cartridge, Plastic Dropper and Sample Collection Tube should be used for one specimen only.

12. Do not smoke, eat, or drink in areas in which specimens or test kit are handled.

13. Fecal specimen, used Test Cartridge, Plastic Dropper and Sample Collection Tube are potentially infectious. Proper safety techniques, handling and disposal methods should be followed in accordance with standard procedures and relevant regulations observed for microbiological hazard materials.

14. The Finicare™ H.pylori Ag Test should not be used as absolute evidence for the diagnosis of H. pylori infection and demonstrate loss of H. pylori antigen following treatment. The results should be interpreted by the physician along with clinical findings and other laboratory test results.

15. If you have any questions or need help, please contact the local distributor to solve problems timely.

16. Notice to the users: Any serious incident that has occurred in relation to the Finicare™ H.pylori Ag Test shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

MATERIALS

Materials Provided

1. 25 individual Sealed Pouches, each containing:
 - 1 Test Cartridge
 - 1 Desiccant Pouch
2. 1 ID Chip
3. 1 Leaflet with Instructions for Use
4. 25 Sample Collection Tubes including extraction buffer
5. 10 Plastic Droppers
6. 1 Leaflet with Quick Manual

Materials Required But Not Provided

Function	Material Name	Note
Test instrument	Finicare™ FIA Meter Plus	Model No.: FS-113
	Finicare™ FIA Meter II Plus SE	Model No.: FS-114
	Finicare™ FIA Meter III Plus	Model No.: FS-205

Specimen sampling	Specimen Container	Collection	For feces specimen
Timekeeping for specific test step	Timer		/

STORAGE AND STABILITY

1. Store test kit for 24 months at 4~30°C.
2. Do not remove the Test Cartridge from the pouch until use. The Test Cartridge should be used within 1 hour once opened.

SPECIMEN COLLECTION AND PREPARATION

The test only can be performed with human feces.

It is recommended that human feces should be tested immediately. If the specimen is not tested within 6 hours, it can be stored at 2 ~ 8 °C for 3 days. For long term storage, the sample may be stored for up to 6 months at -20°C.

Operation of the sample collection:

(1) Solid sample:

Unscrew the sampling stick of the Sample Collection Tube, and then carefully remove the sampling stick, taking care not to splash the solution out of the Sample Collection Tube. Use the sampling stick to sample at 6 different parts of the feces. The spiral sampling part needs to be immersed in the sample, and then inserted back into the Sample Collection Tube and tightened. Shake the Sample Collection Tube more than 10 times to allow the extraction buffer to fully dilute the human fecal sample. The sample should be tested immediately after extraction.

(2) Liquid sample:

Unscrew the screw cap of the Sample Collection Tube, use a Plastic Droppers to absorb the liquid human fecal sample and add 2 drops in the Sample Collection Tube. Tighten the screw cap and shake the Sample Collection Tube more than 10 times to allow the extraction buffer to fully dilute the human fecal sample. The sample should be tested immediately after extraction.

Note: Bring specimens to room temperature before testing. Specimens should not be frozen.

TEST PROCEDURE

For complete information and operating procedures, please refer to Finicare™ FIA Meters Operation Manual. Tests should be performed at room temperature.

Step 1: Preparation

Ensure that the Test Cartridge and extraction buffer are restored to room temperature. Ensure that the lot number of the Test Cartridge matches ID Chip as well as the extraction buffer. Insert ID Chip into Finicare™ FIA Meters.

Step 2: Sampling

Collect the sample correctly according to the operation of the Sample Collection Tube.

Step 3: Mixing

Shake the Sample Collection Tube up and down more than 10 times until the sample on the stick is dissolved.

Step 4: Loading

Unscrew the end cap of the Sample Collection Tube, discard the first 3 drops, and then add 3 drops of sample mixture vertically to the sample well of the Test Cartridge.

Step 5: Testing

There are two test modes for Finecare™ FIA Meters, Standard Test mode and Quick Test mode. Please refer to the Operation Manual of Finecare™ FIA Meters for details.

a) For Standard Test Mode: For FS-113, FS-114, Insert the Test Cartridge into the Test Cartridge holder of Finecare™ FIA Meters right after adding sample mixture to the sample well. Press “Start Test” to start test. For FS-205, press “Test” then input the specimen types, press “Start” then insert the Test Cartridge into the Test Cartridge holder of Finecare™ FIA Meters right after adding sample mixture to the sample well to start test. The test result will be displayed on the screen after 10 minutes.

b) For Quick Test Mode: Set the timer and count down right after adding sample mixture into the sample well and leave the Test Cartridge at room temperature for 10 minutes. Then immediately insert the Test Cartridge into the holder of Finecare™ FIA Meters. Press “Start Test” to start test (Apply to FS-113, FS-114). The instrument will automatically start to scan the Test Cartridge immediately. Read the results on the display screen of Finecare™ FIA Meters.

Step 6: Printing

If needed, test result can be printed by clicking “Print”.

INTERPRETATION OF RESULTS

Finecare™ FIA Meters displays the test result automatically on the screen. The result will be displayed as cut-off index (COI).

COI	Result
< 1.0	Negative
≥ 1.0	Positive

Invalid: When the Finecare™ FIA Meters flag that no sample or sample volume is insufficient, it indicates an invalid test (the signal on the scan strip is below the preset minimum signal). Please retest.

QUALITY CONTROL

Each Finecare™ H.pylori Ag Test contains internal control that satisfies routing quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test cartridge was inserted and read properly by Finecare™ FIA Meters. An invalid result from the internal control causes an error message on Finecare™ FIA Meters indicating that the test should be repeated.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing human feces only.
2. This test has been verified for healthcare professionals use.
3. Refer to point 6 of the PRECAUTIONS in this instruction for requirements of training and qualifications required by the users. Note that this test is not used for self-testing.
4. The results of Finecare™ H.pylori Ag Test should be evaluated with all available clinical and laboratory data.
5. The false positive results include non-specific adhesion of some components in specimen that have similar epitopes to bind captured and detector antibodies.
6. In the case of false negative results, the most common factors are: non-responsiveness of antigen to the antibodies by that certain unknown components are masking its epitope, such that antigen cannot be seen by the antibodies; instability of H.pylori Ag, resulting in degradation with time or temperature, such that they become no longer recognizable by antibodies.
7. Other factors may interfere with Finecare™ H.pylori Ag Test and may cause erroneous results. These include technical or procedural errors, as well as presence of interfering substances in feces specimens.

PERFORMANCE CHARACTERISTICS

Limit of detection

Limit of detection: 3×10^4 CFU/mL.

Comparability with reference product

Reagents		Commercial kit		
		Positive	Negative	Total
Finecare™ H.pylori Ag Test	Positive	57	2	59
	Negative	1	114	115
	Total	58	116	174

- Sensitivity: 98.28% (90.86%~99.70%)
- Specificity: 98.28% (93.93%~99.53%)

Analytical Specificity

Interfering substance

The following substances do not interfere with the test results at the indicated concentrations:

Substance	Acceptable range
Hemoglobin	≤ 12.5mg/mL

Cross-Reactivity

There was no significant cross-reactivity with the test results at the indicated concentrations:

Substance	Acceptable range
Escherichia coli	≤ 1×10^7 CFU/mL
Enterococcus faecalis	≤ 1×10^7 CFU/mL
Bacillus subtilis	≤ 1×10^7 CFU/mL
Campylobacter jejuni	≤ 1×10^7 CFU/mL
Clostridium perfringens	≤ 1×10^7 CFU/mL
Proteus mirabilis	≤ 1×10^7 CFU/mL
Candida albicans	≤ 1×10^7 CFU/mL

Precision

Precision was determined by testing negative and positive specimens. The negative agreement rate and the positive agreement rate was 100%.

BIBLIOGRAPHY OF SUGGESTED READING

1. Amieva M, Peek R M. Pathobiology of Helicobacter pylori-Induced Gastric Cancer[J]. Gastroenterology, 2016, 150(1).
2. Brown L M. Helicobacter Pylori: Epidemiology and Routes of Transmission[J]. Epidemiologic Reviews, 2000, 22(2):283-297.
3. Kamiya S. Pathogenesis of Helicobacter pylori[J]. Journal of Intestinal Microbiology, 2006, 20(4):309-319.

INDEX OF SYMBOLS

	Consult instructions for use		Contains sufficient for <n> tests		Date of manufacture
	In vitro diagnostic medical device		Use-by date		Do not re-use
	Temperature limit		Batch code		Catalogue number

	Keep away from sunlight		Keep dry		Manufacturer
	CE marking		Authorized representative in the European Community/European Union		



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