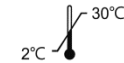




# "IF" Fecal Occult H. pylori Antigen Test (Non-Sterile)



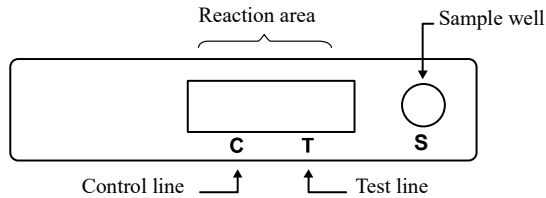
Article number: B0310

## Intended Use:

"IF" Fecal Occult H. pylori Antigen Test kit is a lateral flow immunoassay reagent used for qualitative detection of *H. pylori* antigens in human fecal specimens to assist in the diagnosis of *H. pylori* infection.

## 1. Test Principle

This test is an assay for detecting *H. pylori* antigen using human feces sample. Immunochromatographic assay technology is utilized as its measurement principle. The test consists of a cassette device containing anti-*H.pylori* Ag monoclonal antibodies directed against *H. pylori* antigen. The sample well contains the anti-*H.pylori* antigen monoclonal antibody binding colloidal particles. If the *H. pylori* antigen is present in the specimen, the solubilized conjugate migrates with the sample by passive diffusion and the conjugate and sample material come into contact with the anti-*H.pylori* antibodies adsorbed onto the nitrocellulose. A red or pink line will appear on the test line T, which is a positive reaction. On the contrary, when there is no *H. pylori* antigen in the specimen, no line will appear on the test line T, which is a negative reaction. In each reaction, the control line C should produce a red or pink line.



## 2. Reagents and Materials

Test cassette	20 pcs
Collector	20 pcs

## 3. Storage, Shelf Life

The kits are to be stored in an environment of 2° to 30°C and can be used until expiry date (indicated on the outer box).

## 4. Material Needed but Not Supplied

1. Timer or clock
2. Disposable gloves
3. Sample collection container

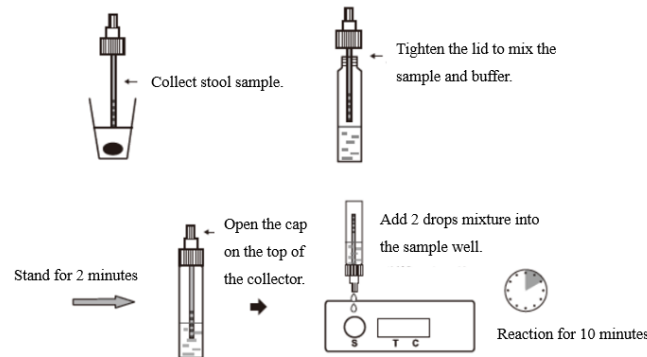
## 5. Specimen Source and Collection Method

1. The stool sample must be collected in the collector included in the kit and a sufficient amount of stool must be collected in the sample.

2. If the specimen needs to be transported, it should be packaged in accordance with local regulations on the transportation of pathogens.
3. The best results will be obtained if the test is performed within 6 hours of collection. If the stool sample cannot be tested in time, it can be stored at 2-8°C for 3 days; for long-term storage, the sample should be stored below -20°C and the sample must be returned to room temperature before testing.

## 6. Test Procedure

1. Unscrew the lid of the collector, then randomly insert the collection stick into at least 3 different parts of the stool sample to collect about 50 mg of stool (equivalent to 1/4 the size of a pea). Avoid sampling by digging, as shown below; do not collect watery stool caused by diarrhea.
2. Tighten the lid of the collector, then shake vigorously to mix stool sample with the buffer in the collector, and leave the tube for 2 minutes, as shown below.
3. Before using the reagent, return it to room temperature. Remove the test kit from the foil pouch and use within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
4. Hold the collector vertically, open the cover on the top of the collector, turn the collector upside down, and add 2 drops (about 80µL) of the mixture into the sample area (S) of the cassette, see the figure below.
5. Read the results after 10 minutes by visually confirming the presence of red/pink lines on the reaction area of the cassette. If red/pink lines appear in the test region (T) and the control region (C), the result can be judged as positive. **Do not read results later than 20 minutes after testing.**



## 7. Interpretation of Results

### • Positive results (+)

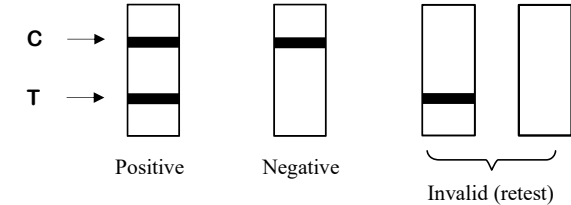
Positive: red/pink colored lines appear in the test region (T) and the control region (C).

### • Negative results (-)

Negative : a red/pink line appears in the control region and no red/pink line is visible in the test region (T).

## • Invalid (retest)

In case that no red/pink line appears in the control region (C), even with a red/pink line showing in the test region (T), the test must be considered invalid and a retest should be performed.



## 8. Cautions on Interpretation of Results

1. When testing the presence of *H. pylori* antigen in the feces of the subject, the test procedure and test result interpretation in the reagent manual must be strictly followed. Failure to follow the operating instructions may cause the wrong results.
2. The "IF" Fecal Occult H. pylori Antigen Test is for in vitro diagnostic use only and is used to qualitatively detect whether human fecal specimens contain *H. pylori* antigen. The color intensity of the test line has no linear correlation with the antigen concentration in the specimen.
3. The "IF" Fecal Occult H. pylori Antigen Test can only show the presence of *H. pylori* antigen in stool specimens and should not be used as the sole criterion for evaluating whether *H. pylori* is the cause of peptic or duodenal ulcers.
4. If the *H. pylori* antigen test is negative and does not match the clinical symptoms, it is recommended to perform further tests. A negative result cannot rule out the possibility of *H. pylori* infection.
5. As with all diagnostic tests, clinical symptoms must be further evaluated by a clinician to confirm the diagnosis of *H. pylori* infection.
6. After certain antibiotic treatments, the concentration of *H. pylori* antigen may decrease to below the limit of the detection concentration of the reagent. Therefore, diagnosis should be performed with caution during antibiotic treatment.
7. This reagent has been tested and proven to be able to detect *H. pylori* strains isolated from medical institutions in Taiwan.

## 9. Precision

Intra-batch analysis and inter-batch analysis used the "IF" Fecal Occult H. pylori Antigen Test, using 3 batches of the same negative, low-concentration positive, medium-concentration positive and high-concentration positive specimens and repeated testing 15 times. The accuracy of the test results was above 99%.



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## 10. Sensitivity, specificity and cross-reactivity

The "IF" Fecal Occult H. pylori Antigen Test was evaluated with specimens obtained from symptomatic and asymptomatic individuals and demonstrated a sensitivity of >99.9% and a specificity of 98.1% relative to endoscopy-based methods.

Method	Result	Endoscopy-based methods		Total
		Positive	Negative	
"IF" Fecal Occult H. pylori Antigen Test	Positive	78	2	80
	Negative	0	101	101
Total		78	103	181

Relative Sensitivity:  $78/78 = >99.9\%$  (95%CI\*: 96.2%~100.0%)

Relative Specificity:  $101/103 = 98.1\%$  (95%CI\*: 93.2%~99.8%)

Accuracy:  $(78+101)/(78+103) = 98.9\%$  (95%CI\*: 96.1%~99.9%)

\*CI: Confidence Interval

## 11. cross-reactivity

The cross reaction of the "IF" Fecal Occult H. pylori Antigen Test with organisms at a concentration of  $1 \times 10^9$  CFU/mL showed negative results for the following microorganisms:

<i>Candida albicans</i>	<i>Klebsiella pneumonia</i>
<i>Enterococcus faecium</i>	<i>Proteus mirabilis</i>
<i>E.coli</i>	<i>Pseudomonas aeruginosa</i>
<i>Group A Streptococcus</i>	<i>Staphylococcus aureus</i>
<i>Group B Streptococcus</i>	

■ Revision: 1<sup>st</sup> edition

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## ⚠ Precautions / Notes

- All reagents of this kit are strictly intended for in vitro diagnostic and professional use only. Do not use after the expiration date.
- Do not eat, drink or smoke in sample handling area.
- If the reagent foil packaging is damaged, do not use it for testing.
- All specimens should be handled as if they were infectious agents.  
Precautions against microbiological hazards should be observed during the operation, and standard procedures for proper specimen handling should be followed.
- When testing specimens, you should wear a lab coat, disposable gloves, and goggles.
- After use, dispose the product and samples in accordance with applicable medical waste management guidelines.
- Improper storage conditions may affect the results.
- The buffer contains sodium azide, avoid contact with eyes and mucous membranes. If contact occurs accidentally, rinse with water and seek medical attention immediately.