

For detection of *Helicobacter Pylori* antigen in stool.
Only for *In Vitro* diagnostic use.

ORDER INFORMATION

REF	Cont.
HYPC 10	10 Test
HYPC 25	25 Test

CLINICAL SIGNIFICANCE

Helicobacter pylori (*H. pylori*) was initially isolated by Warren and Marshall from biopsy samples taken from patients suffering from active chronic gastritis. In fact, it is now clear that *H. pylori* is the principle etiologic agent in type B gastritis (chronic active antral gastritis) pathology for which it appears to be the triggering and perhaps aggravating factor. Increasing data are being accumulated regarding the fundamental role of *H. pylori* in active chronic gastritis, in gastric ulcer and in duodenal ulcer and its close correlation with gastric lesions. *H. pylori* is isolated in culture medium and examined by microscopy after staining or is detected by urease test. Both these techniques are lengthy to implement and their sensitivity and specificity have yet to be demonstrated. The immunochromatographic techniques (rapid) for the detection of antibodies specific to *H. pylori* has substantially resolved these problems, ensuring a serological monitoring in a very short space of time using simple, highly specific technology without recourse to invasive techniques. The stool test for *H. pylori* can be utilized as a rapid screening process for large populations of patients and highly indicated in the early diagnosis of *H. pylori* infection as the immune response can often precede clinical manifestations of disease. From a diagnostic point of view, a high stool-level antigen against *H. pylori* must be interpreted as an indication of type B asymptomatic gastritis.

PRINCIPLE

H. pylori Antigen test is a rapid test for the qualitative detection of *Helicobacter pylori* antigens in human stool. This test kit is intended as an aid in the diagnosis of *H. pylori* infection in patients with gastrointestinal symptoms. The *H. pylori* test contains a membrane strip, which is pre-coated with *H. pylori* capture monoclonal antibodies on test band region. The *H. pylori* antibody- colloid gold conjugate and extracted stool sample move along the membrane chromatographically to the test region (T) and form a visible line as the antibody-antigen-antibody gold particle complex forms with high degree of sensitivity and specificity. This test device is marked with the letters T (Test Line) and C (Control Line) on the surface of the case. Both the Test Line and Control Line in result window are not visible before applying any samples. The Control Line is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working.

KIT COMPONENTS

Test Cassette Device, Assay Buffer, Dropper and Instructions for Use

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Does not use after the expiration date.
- Wear protective gloves while handling specimens wash thoroughly afterwards.
- The device is sensitive to humidity as well as heat. Therefore, take out the device from seal pouch before test.
- Do not mix reagents from different lot.
- Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
- Follow the testing procedure exactly as mention in the insert.

STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use.
DO NOT FREEZE.
- Do not use beyond the expiration date.
- Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION

- Stool samples must be taken as soon as the symptoms appear.
- Stool specimens should be collected in containers that do not contain media, preservatives, animal serum or detergents as any of these additives may interfere with the test.
- Specimens may be stored at 2-8°C for 2 days without interfering with the assay performance.
- For long-term storage of specimens, -20°C or colder is recommended. Repeated freezing and thawing of specimens is not recommended and may cause erroneous results. Do not store specimens in self-defrosting freezers.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

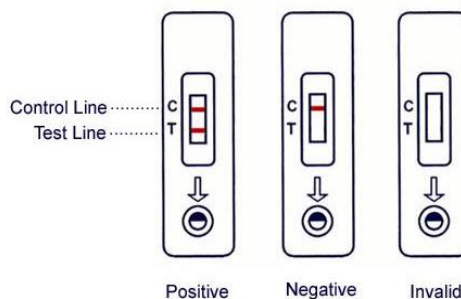
DIRECTIONS FOR USE

Allow test device, stool and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

- Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
- Take the pinch of stool sample using applicator and add in to the 2 ml Assay Buffer in glass test tube. Mix well then kept for 10 minute. Add 2-3 drops from the upper layer of the extract into the sample well.
- The result should be read after 15 minutes but not more than 20 minutes.

Note: Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS



NOTE: A low *H. pylori* concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 30 minutes.

POSITIVE:

Two distinct red lines appear. One line should be in the control region (C) and the other lines should be in the test region (T).

- NOTE:** The intensity of the red color in the test line region (T) will vary depending on the concentration of *H. pylori* antigens present in the specimen. Therefore, any shade of red in the test region (T) should be considered positive.

NEGATIVE

One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your supplier. .

LIMITATIONS

1. H. Pylori Test Device (Stool) is for *in vitro* diagnostic use only. This test should be used for the detection of H. pylori antigens in human stool only.
2. H. Pylori Test Device (Stool) will only indicate the presence of H. pylori antigen in the specimen and should not be used as the sole criteria for the diagnosis of H. pylori infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of H. pylori infection.

INTERNAL QUALITY CONTROL

The "Control Line" is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working. It confirms sufficient specimen volume and correct procedural technique. A clear background is also required

PERFORMANCE CHARACTERISTICS

The ACCUCARE® ONE STEP H.PYLORI ANTIGEN RAPID TEST has been evaluated with positive and negative samples and data are as follow:








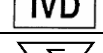



Specimen	Positive	Negative	Sensitivity
Positive	27	3	90%

Specimen	Positive	Negative	Specificity
Negative	10	90	90 %

BIBLIOGRAPHY

1. Marshall B.J. et al. Pyloric Campylobacter infection and gastroduodenal disease. *Med. J. Aust.* 142: 439-444 (1985).
2. Varia, D. and Holton, J. Serum immunoglobulin G antibody levels for *Campylobacter pylori* diagnosis. *Gastroenterology.* 97: 1069–1071 (1989).
3. Lambert, J.r., Lin, S.K. and Aranda-Michel, J. *Helicobacter pylori*. *Scand. J. Gastroenterol.* 30 suppl 208: 33-46 (1995).
4. Evans, D.J., Evans, D.G., Graham, D.Y. and Klein, P.D. A. Sensitive and specific serologic test for detection of *Campylobacter pylori* infection. *Gastroenterology.* 96: 1004–1008 (1989).

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer		Do not reuse
	For <i>in vitro</i> Diagnostic use only		Keep Dry
	Tests per Kit		Do Not Use if Damaged