H. pylori ANTIGEN

METHOD – LATERAL FLOW IMMUNOASSAY
PRODUCT CODE – RC05

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

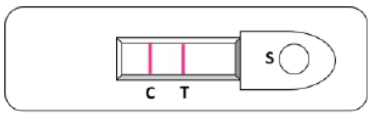
INTENDED USE: Test for qualitative detection of Helicobacter pylori antigen in stool sample.

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, Buffer saline , Dropper and Instructions for Use

PRECAUTIONS

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

STORAGE & STABILITY

The kit can be stored at room temperature or refrigerated (2-30 °C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

1. Stool samples must be taken as soon as the symptoms appear.
2. 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.
3. Specimens may be stored at 2-8 ^{0}C for 2 days without interfering with the assay performance.
4. For long-term storage of specimens, -20 ^{0}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.
5. If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

TEST PROCEDURE

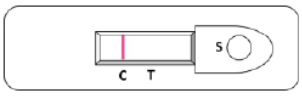
Allow test cassette, specimen, and/or buffer to equilibrate to room temperature (15-30 °C) prior to testing.

1. 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.
2. Take the pinch of stool sample using applicator and add in to the 2 ml buffer saline in glass test tube. Mix well then kept for 10 minute. Add 2 drops (80 to 100µLs) from the upper layer of the extract into the sample well.
3. The result should be read after 20 minutes but not more than 30 minutes.

Note: Do not interpret the result after 30 minutes.

INTERPRETATION OF THE RESULTS

NEGATIVE RESULT:



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

POSITIVE RESULT:

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 colour 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.

INVALID TEST:

The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the likeliest reasons for control line failure. Repeat the test using a new test device.

LIMITATIONS OF THE TEST

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

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).

SYMBOLS:


Read Instruction for use

In Vitro Diagnostic Use Only


Manufactured by


Expiry Date


Storage Temperature

ANAMOL LABORATORIES PVT. LTD.
61, Genesis Industrial Township, Kolgaon,
Palghar – 401 404. India.
Customer Care: +91-9823388695.

admin@anamollabs.com
exports@anamollabs.com
www.anamollabs.com

ISO 9001 : 2015
ISO 13485 : 2003
GMP
CE