H.Pylori antigen Rapid Test Kit (colloidal gold)

INTENDED USE

H. pylori Antigen Rapid Test kit is an in vitro qualitative immunochromatographic assay for the rapid detection of H.pylori antigens in human stool specimen. The test results are intended to aid in the diagnosis of H. pylori infection, to monitor the effectiveness of therapeutic treatment and to confirm the eradication of H.pylori in peptic ulcer patients.
It only takes ten minutes to visually see the test results

SUMMARY

H.pylori is a corkscrew-shaped, gram-negative rod that lives in the mucous layer of the stomach. H. pylori infection is now accepted as the most common cause of gastritis, and is etiologically involved in gastric ulcer, duodenal ulcer, gastric adenocarcinoma and primary gastric B-cell lymphoma.

The organism is very common, infected at least half of the world's population. H. pylori infection is typically acquired in childhood. Once acquired, infection persists chronically, probably continuing in the stomach throughout life. The damage to gastric structure and function of stomach is constant and direct. Approximately one in six of H. pylori infection develops peptic ulcer disease and a small portion of H.pylori infection leads to gastric cancer. The diagnostic tests for H. pylori can be classified into two categories: Invasive and Noninvasive tests. Direct detection by invasive test procedures requires an endoscopy and biopsy specimens from antrum andstomach body .

The presence of H. pylori is then confirmed by direct culture, histological examination or rapid urease test. The endoscopy and biopsy specimens offer direct detection of active H. pylori infections. Although the procedure is highly specific and high positive predictive value, the cost and discomfort to the patients are very high.

PRINCIPLE

H. pylori Antigen Rapid Test Kit is a sandwich solid phase immunochromatographic assay. To perform the test, an aliquot of diluted stool sample is added to the sample well of the test cassette. The sample flows through a label pad containing H. pylori antibody coupled to redcolored colloidal gold. If the sample contains H. pylori antigens, the antigen will bind to the antibody coated on the colloidal gold particles to form antigen-antibody-gold complexes. These complexes move on the nitrocellulose membrane by capillary action toward the test line region on which H. pylori specific antibodies are immobilized.

As the complexes reach the test line, they will bind to the antibody on the membrane in the form of a line. A second red control line will always appear in the result window to indicate that the test has been correctly performed and the test device functions properly. If H. pylori antigen is not present or lower than the detection limit of the test, only the control line will be visible. If the control line dose not developed, the test is invalid.

PRECAUTIONS

1. This kit is for in vitro use only. Do notswallow.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.
6. Discard after use. The test device cannot be used more than once.
7. The extraction tube are single use items – do not use with multiple specimens.
8. All specimens should be treated as potentially infectious diseases. Protection glove should be worn when handling the specimen. Wash hands thoroughly afterwards.
9. Avoid splashing or aerosol formation.
10. The used device, swab and extraction tube have the infectious risk. The process of disposing the diagnostic must follow the local infectious disposal law or laboratory rule.

MATERIAL

Material provided

1. 30 test devices, each one is sealed in a bag.
   - Test device
   - Desiccant pouch
2. 30 Toilet bottle contains wash buffer-0.8ml
3. 1 package insert (Instruction for Use)

Material Required But Not Provided

- Timer

SPECIMEN COLLECTION AND STORAGE

1. 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 One Step H. pylori Antigen rapid test kit
2. Specimens may be stored at 2-8 ℃for 3 days without interfering with the assay performance.
3. For long-term storage of specimens, 2-20 ℃ or colderis recommended.
4. Repeated freezing and thawing of specimens is not recommended and may cause erroneous results. Do not store specimens in self-defrosting freezers.

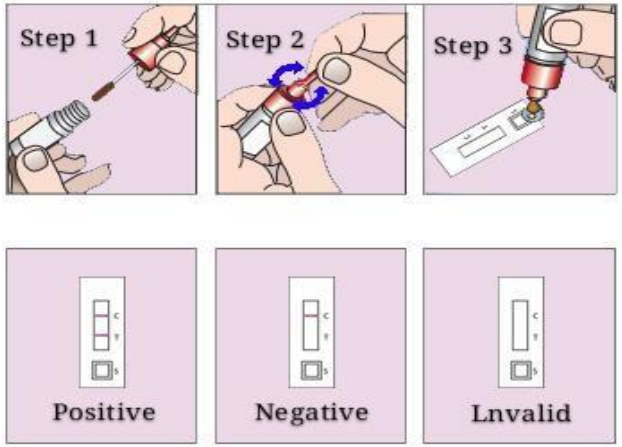
TEST PROCEDURE

1. Unscrew the sample bottle, use the attached applicator stick attached on the cap to transfer small piece of stool (5-6 mm in diameter; approximately 100 mg – 200 mg/0.1-0.2 g) into the sample bottle containing specimen preparation buffer. Replace the stick in the bottle and tighten securely. Mix stool sample with the buffer thoroughly by shaking the bottle for a few seconds.

2.Hold the sample bottle upright with the tip point toward the direction away from the test performer, Unscrew cutting-edge

3.Hold the bottle in a vertical position over the sample well of the Cassette, deliver 3 drops (120 -150 L) of diluted stool sample to the sample well.

Read the result within 10 to 15 minutes. A strong positive sample may show result earlier. Test results after 15 minutes may not be accurate.



INTERPRETATION OF RESULTS

Positive:
A distinct pink colored band appears on test line regions, in addition to a pink line on the control line region.

Negative :
No line appears in the test line region. A distinct pink line shows on the control line region.

Invalid:
The control line next to the test line does not become visible within 10 minutes after the addition of the sample.

PERFORMANCE CHARACTERISTICS

Accuracy

One Step H.pylori Antigen rapid test kit was evaluatd on 1049 stool samples. The test results were compared with an approved predicate kit.

H. Pylori Antigen Rapid test kit	Predicate Kit		Total
	Positive	Negative	
Positive	508	11	519
Negative	5	525	530
Total	513	536	1049

Out of five hundred and thirteen (513) samples that were tested positive by the predicate kit, five hundred and eight (508) were positive on H. Pylori Antigen Rapid test kit Insta test. Out of five hundred and thirty six (836) samples that were tested negative by the predicate kit, five hundred and twenty five (525) were negative on H. Pylori Antigen Rapid test kit Sixteen (16) samples that have disagreed results were verified by ELISA. Seven (7) samples have the results agreed with H. Pylori Antigen Rapid test kit while nice (9) samples agreed with the predicate kit. The agreement with the predicate kit is summarized as below.

Agreement of positive = 508/513 = 99.03%
Agreement of Negative = 525/536 = 97.95%
Total Agreement = 1033/1049 = 98.47%

Assay Specificity

Following bacterial and viral strains were used to test the specificity of H. Pylori Antigen Rapid test kit . Positive and negative controls spiked with the bacteria or virus at the indicated concentration showing no interference on the test result.

Adenovirus type 40	$1x10^6$ TCID50
Adenovirus type 41	$1x10^6$ TCID50
Rotavirus Wa	$1x10^6$ TCID50
Campylobacter jejuni	$7.63x10^7$CFU/ml
Candida albicans	$1x10^8$CFU/ml
Clostridium perfringens A	$1x10^8$CFU/ml
Citrobacter freundii	$1x10^8$CFU/ml
Enterococcus faecalis	$1x10^8$CFU/ml
Escherichia coli	$1x10^8$CFU/ml
Klebsiella pneumonia	$1x10^8$CFU/ml
Listeria monocytogenes	$1x10^8$CFU/ml
Moraxella catarrhalis	$9.9x10^6$CFU/ml
Neisseria gonorrhoeae	$1x10^8$CFU/ml
Pseudomonas aeruginosa	$1x10^8$CFU/ml
Stapylococcus epidermidis	$1x10^8$CFU/ml
Stapylococcus aureus	$1x10^8$CFU/ml
Shigella flexneri	$1x10^8$CFU/ml
Shigella sonnel	$1x10^8$CFU/ml
Steptococcus dysgalactiac	$1x10^8$CFU/ml
Streptococcus agalactiac	$1x10^8$CFU/ml
Streptococcus pyogenes	$1x10^8$CFU/ml

QUALITY CONTROL

1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.

2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which is not provided with this test kit may be commercially available.

LIMITATIONS OF PROCEDURE

1. The test is for qualitative detection of H. pylori antigen in stool sample and dose not indicate the quantity of the antigens.

2. The test is for in vitro diagnostic use only.

3. The test result should be used only to evaluate with patient with signs and symptoms of gastrointestinal disease. A definitive clinical diagnosis should only be made by the physician after all clinical and laboratory finding have been evaluated.

EXPECTED VALUES

H.pylori infects more than half the people in the world. The prevalence of the infection varies among countries and among different groups within the same country. The prevalence rate in the United State suggests an incidence of infection of 2%. The lifetime prevalence of peptic ulcer disease is about 12% in men and 9% in women. Studies have found that more than 90% of patients with duodenal ulcer and 80% of patients with gastric ulcer are infected with H. Pylori Antigen Rapid test kit detects the presence of H.pylori antigens in stool specimens. Expected values for any given population should be determined for each laboratory. The positivity rate of any given laboratory may vary depending on geographic location, ethnic group, and living environment.

PRECAUTIONS

1. For in vitro diagnostic use.

2.Wear protective glove while handling kit components and test specimens.

3.Patient specimens and inactivated Positive Control may contain infectious agents and should be handled and disposed of as potential biohazards.

4. Do not use kit components beyond expiration date.

5.Dispose all used materials in appropriate container. Treat as potential biohazard.

INDEX OF SYMBOLS

	See instruction for use		Tests per kit		Manufacturing
	For *in vitro* diagnostic use only		Expiry date		Do not reuse
	Store between 2 ~ 30 ℃	LOT	Batch number	REF	Catalog #
	Keep away from sunlight		Keep dry	EC REP	Authorized Representative

our company is certified by ISO quality system