INTENDED USE

H. Pylori is a rapid, one-step lateral-flow immunoassay for the qualitative detection of *Helicobacter pylori (H. pylori)* in feces as an aid in the detection of H. pylori infection in patients with clinical symptoms of gastrointestinal disease.

SUMMARY AND EXPLANATION

Helicobacter pylori is associated with a variety of gastrointestinal diseases included non-ulcer dyspepsia, duodenal and gastric ulcer and active, chronic gastritis[1,2]. In patients with signs and symptoms of gastrointestinal diseases the prevalence rates for H. pylori infection can exceed 90%. Recent studies indicate an association of H. pylori infection with stomach cancer[3].
Patients colonized with H. pylori elicit a specific antibody response [4,5,6] which is used as a diagnostic aid and for monitoring the disease state during a treatment. Several treatment using antibiotics in combination with bismuth compounds have been shown to be effective in treating active H. pylori infection. Successful eradication of H. pylori is associated with clinical improvement in patients with gastrointestinal diseases providing a further evidence[7].

PRINCIPLE OF THE TEST

The H. Pylori Test device consists of a chromatographic absorbent membrane strip pre-coated (Test zone) with anti-H.Py antigen antibody.
In the test procedure, the specimen extracted is added to the sample well and allowed to migrate via the capillary action. When migrating along the chromatographic membrane, H. pylori in the specimen will be reacted with an anti-H. Pylori antibody dyed with gold particles and migrates up. If there is *H. pylori* specific antigen present in the sample, a rose-pink color band appears in the Test zone. In the absence of *H. pylori* antigen, there is no formation of a rose-pink color band in the Test zone. Unbound conjugate pass by and binds to the reagents in the Control zone, producing a rose-pink color band, demonstrating that the reagents and device are functioning correctly.

MATERIALS PROVIDED

1. Test Devices
2. Extraction buffer vial
3. Instructions-For-Use (IFU)

STORAGE AND STABILITY

The H.P. test device may be stored at an ambient temperature of 15 - 30ºC for 12 months.

SPECIMEN COLLECTION

1. Collect a random sample of feces in a clean, dry receptacle.
2. Unscrew the top of the extract buffer vial.
3. Insert the stick into the fecal specimen at several different sites.
4. Remove excess sample from the stick by gently wiping with an absorbent tissue.
5. Replace the stick in the tube and tighten securely.
6. Shaking the tube violently.

The specimen is now ready for testing, transportation or storage. Samples should be tested within one week of collection.

The H. Pylori is performed using 2 drop of extraction specimen from feces.

TEST PROCEDURE

Prior to use, bring all test components and patient samples to room temperature.

Test Procedure For Dipstick:

1. Remove the "Test Device" from its foil wrapper
2. Immerse the strip into the extraction sample vial with the arrow pointing the sample. The sample level should not be higher than the arrow pointed line.
3. You may leave the strip in the vial or take the strip out after a minimum of 20 seconds or until you begin to see the migration of the sample into the result area and lay the strip on a flat non-absorptive surface.
4. Read the result at 10 minutes.

Test Procedure For Cassette:

1. Remove the 'Test Device' from its foil wrapper
2. Add 2 drops of patient's extraction sample on the (S) well as soon as the sample reaches the view window, start timing.
3. Read the result at 10 minutes.

INTERPRETATION

Positive Result:

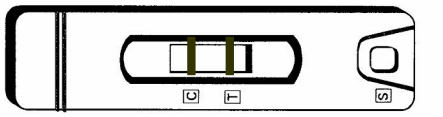
If there is a rose-pink color band in the control region (marked with a "C"), ***and*** a rose-pink color band in the test region (marked with a "T"), *H. pylori* antigen are present and the specimen is positive.

Negative Result:

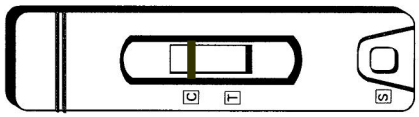
The absence of a color band in the test region next to the letter "T" indicates the absence of any detectable *H. pylori* antigens.

Invalid Result:
If a color band does not appear in the control region "C", the test results are invalid. The sample may have been added to the wrong window, or the test device may have been deteriorated. This specimen should be retested using new Test Device.

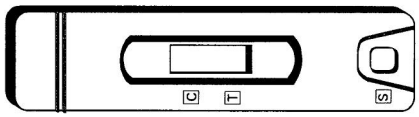
POSITIVE RESULT FOR TEST CARD:



NEGATIVE RESULT FOR TEST CARD:



INVALID RESULT FOR TEST CARD



NOTE:
As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after evaluation of all clinical and laboratory findings.

REFERENCES:

1. Marshall,B.J.et.al. Pyloric Campylobacter infection and gastroduodenal disease. Med. J. Australia. 149:439-44, 1985
2. Soll,A.H. Pathogenesis of peptic ulcer and implications for therapy. New England J. Med.322:909-916,1990
3. Parsonnet,J.et.al. Helicobacter pylori infection and the risk of gastric carcinoma. New England J. Med. 325:1127-31,1991
4. Ansong,R. et.al. Evaluation of techniques for isolation, subcultivation and preservation of Helicobacter pylori. J.Clin.Micro. 29:51-53,1991
5. Pronovost,A.P.et.al. Evaluation of a new immunodiagnostic assay for Helicobacter pylori antibody detection: Correlation with histopathological and microbiological results. J.Clin.Microbiol.32:46-50,1994
6. Megraud,F.et.al. Seroepidemiology of Campylobacter pylori infection in virious populations. J.Clin.Microbiology. 27:1870-3,1989

7. Marshall,B.J.et.al. Prospective double-blind trial of duodenal ulcer relapse after eradication of Campylobacter pylori. Lancet. Dec.1437-42,1988

Rev1: 6/2/09
Vers. 02102009CM
Revised ~ 5/5/2010~fr