INTENDED USE

H. Pylori is a rapid, one-step lateral-flow immunoassay for the qualitative detection of *Helicobacter pylori (H. pylori)* in faces 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 (optional for cassettes/test cards only)
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

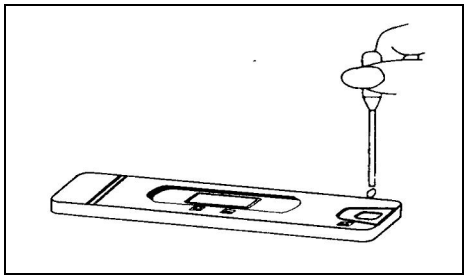
1. Collect a random sample of feces in a clean, dry receptacle.
2. Unscrew the top of the extract buffer vial which contain 2 ml of extraction buffer.
3. Insert the stick into the fecal specimen at several different sites.
4. Replace the stick in the tube and tighten securely.
5. Shaking the tube violently.

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 faces.

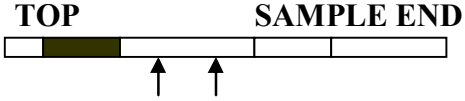
TEST PROCEDURE

1. Remove the "Test Device" from its foil wrapper
2. Add 2 drops (~80 µl) of patient's extraction sample on the S well.
3. Read the result at 10 minutes.



For Test Strip (dipstick):

1. Open the foil pouch at the notch and remove the test device and transfer pipette. Take care not to touch the exposed membrane.
2. Insert the reactive end of the device into sample. Do not immerse the device any deeper into the sample than the maximum level indicated by the line on the device label.
3. Read the result immediately at (10) minutes. Results read after more than 15 minutes have elapsed and should be considered invalid.



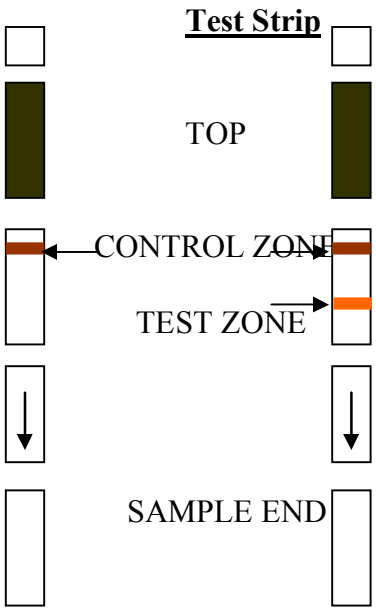
C T
C: CONTROL ZONE
T: TEST ZONE

INTERPRETATION

Positive: If two colored bands are visible within 20 minutes, the test result is positive and valid.

Negative: If test area has no color band and the control area displays a colored band, the result is negative and valid.

Invalid result: The test result is invalid if a colored band does not form in the control region. The sample must be retested, using a new test device.



NEGATIVE **POSITIVE**

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,

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:

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