INTENDED USE

H. Pylori is a rapid, one-step lateral-flow immunoassay for the qualitative detection of total human antibodies specific to *Helicobacter pylori (H. pylori)* in human whole blood/serum/plasma as an aid in the determination 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 H. Pylori antigen (Cag A included).
In the test procedure, the specimen is added to the sample well and allowed to migrate via the capillary action. When migrating along the chromatographic membrane, the antibody specific to H. Pylori in the specimen will be reacted with an H. Pylori antigen dyed with gold particles and migrates up. If there is *H. pylori* specific antibody present in the sample, a rose-pink color band appears in the Test zone. In the absence of *H. pylori* antibodies, 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. Diluent buffer vial (optional for cassettes/test cards only)
3. Instructions-For-Use (IFU)

STORAGE AND STABILITY

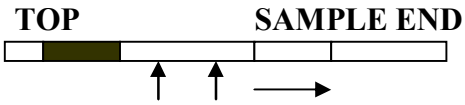
The H. Pylori test device may be stored at an ambient temperature of 15 - 30ºC for 12 months.

SPECIMEN COLLECTION

The H. Pylori is performed using 1 drop of fresh (40ul), whole blood or plasma/serum. Capillary blood may be obtained from the fingertip or earlobe. Fresh venous blood may also be used. Blood samples containing common anti- coagulants and preservatives (e.g. heparin, EDTA, citrate) may be used.

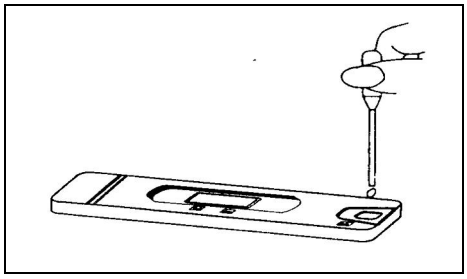
TEST PROCEDURE

1. Remove the "Test Device" from its foil wrapper
2. Add a drop of patient's blood/serum/plasma sample on the S well, wait ~30 second till liquid being absorbed completely, and then add two drops of diluent Buffer from the vial provided.
3. Wait for 10 minutes and read the result.



C **T**
C: CONTROL ZONE
T: TEST ZONE

(*For whole blood test:* An anti-agglutinin must be added into the blood collect vial while withdrawing the blood.)

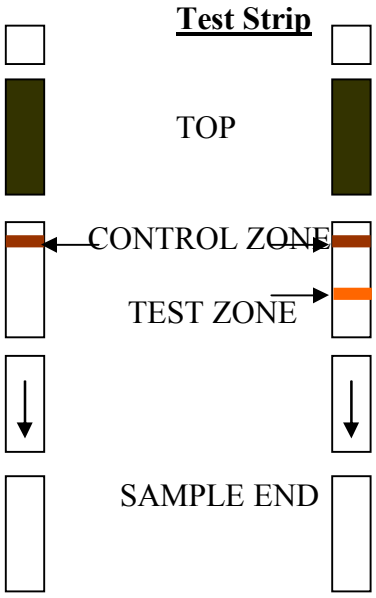


INTERPRETATION

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* antibodies 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* antibodies.

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 deteriorated. This specimen should be re-tested using a new Test Device.



LIMITATION OF THE TEST:

1. H. Pylori One-step test is for *in vitro* use only.
2. If questionable results are obtained, the test should be repeated on a fresh blood specimen.
3. 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.

QUALITY CONTROL

External Controls:

Performance of H. Pylori should be checked for accuracy and batch to batch variation by using known serum pools. These sera should be used in the same way as described in the assay procedure for serum samples. Positive and negative controls can be supplied too. It is recommended that these controls be used at least once with every batch or new shipment.

Internal Controls:

The test device has built-in controls. With each testing there should always be a rose-pink color band in the control zone. If the color band does not appear in the control region, the result should be considered invalid.

PERFORMANCE CHARACTERISTICS

Specificity and Sensitivity:

A study was performed with 175 patient serum samples which included both symptomatic gastrointestinal disorders and samples from non-symptomatic patients. The H. Pylori One-step Test and a traditional enzyme immunoassay were tested on all specimens.

H. PyloriOne-step

		Positive	*Negative*
EIA Test	Positive	158	1
	Negative	1	265

Sensitivity: 99.0%
Specificity: 98.6%

Precision

A. Intra-Assay precision was determined by assaying the 14 replicates of confirmed negative, low and high antibody positive *H. pylori* patient samples.

	Negative	*Low*	*Positive*
No. of determinations	11	11	11
Expected Results	-	+	+
Observed Results	-	+	+

B. Inter-Assay precision was determined by assaying the 16 replicates of confirmed negative, low and high antibody positive *H. pylori* patient's samples at 3 independent test sites with 3 separate lots of reagent. Negative specimens tested negative after 10 minutes each time with all 3 reagent sets at all 3 test sites. Low and high antibody *H. pylori* patient samples tested positive each time with all 3 lots at all 3 test sites. The H. Pylori One-step Test demonstrates excellent reproducibility.

REFERENCES:

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