bi-1-st® of FINLAND

Helicobacter Pylori IgG Test Device

CE IVD

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A rapid, one step test for the qualitative detection of antibodies to Helicobacter pylori (H. pylori) in human serum or plasma.

For professional in vitro diagnostic use only.

INTENDED USE

The *H. pylori* Test Device (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies to *H. pylori* in serum or plasma to aid in the diagnosis of *H. pylori* infection.

SUMMARY

H. pylori is a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum. It is implicated in the etiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcer, non-ulcer dyspepsia and active and chronic gastritis. [1,2]

Both invasive and non-invasive methods are used to diagnose *H. pylori* infection in patients with symptoms of gastrointestinal disease. Specimen-dependent and costly invasive diagnostic methods include gastric or duodenal biopsy followed by urease testing (presumptive), culture, and/or histologic staining.[3] Non-invasive techniques include the urea breath test, which requires expensive laboratory equipment and moderate radiation exposure, and serological methods.[4,5]

Individuals infected with *H. pylori* develop serum antibodies which correlate strongly with histologically confirmed *H. pylori* infection.[6,7] The *H. pylori* Test Device (Serum/Plasma) is a simple test that utilizes a combination of *H. pylori* antigen coated particles and anti-human IgG to qualitatively and selectively detect *H. pylori* antibodies in serum or plasma in just minutes.

PRINCIPLE

The *H. pylori* Test Device (Serum/Plasma) is a qualitative membrane strip based immunoassay for the detection of *H. pylori* antibodies in serum or plasma. In this test procedure, anti-human IgG is immobilized in the test line region of the device. After a serum or plasma specimen is placed in the specimen well, it reacts with *H. pylori* antigen coated particles in the test. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized anti-human IgG. If the specimen contains *H. pylori* antibodies, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain *H. pylori* antibodies, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test device contains *H. pylori* antigen coated particles and anti-human IgG coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use beyond expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect test results.

STORAGE AND STABILITY

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

SPECIMEN COLLECTION AND PREPARATION

- The *H. pylori* Test Device (Serum/Plasma) can be performed using either serum or plasma.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

MATERIALS

Materials Provided

- Test devices
- Disposable specimen droppers
- Package insert

Materials Required But Not Provided

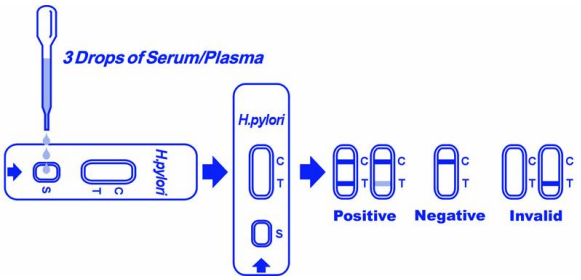
- Specimen collection container
- Centrifuge
- Timer

DIRECTIONS FOR USE

Allow the test device, serum or plasma specimen, and/or controls to equilibrate to room temperature (15-30℃) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 drops of serum or plasma (approx. 100µl) to the specimen well (S) of the test device, and start the timer. Avoid trapping air bubbles in the specimen well (S). Please see the illustration below.
3. Wait for the red line(s) to appear. The result should be read at 10 minutes.

   Note: Low levels of *H. pylori* antibodies might result in a faint line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE*: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

***NOTE:** The intensity of the red color in the test line region (T) will vary depending on the concentration of *HP* antibodies in the specimen. Therefore, any shade of red in

the test region (T) should be considered positive.

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

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.
Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The *H. pylori* Test Device (Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of *H. pylori* antibodies in serum or plasma specimen only. Neither the quantitative value nor the rate of increase in *H. pylori* antibody concentration can be determined by this qualitative test.
2. The *H. pylori* Test Device (Serum/Plasma) will only indicate the presence of *H. pylori* antibodies 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 interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of *H. pylori* infection.

EXPECTED VALUES

The *H. pylori* Test Device (Serum/Plasma) has been compared with Culture/Histology, demonstrating an overall accuracy of 93.2%.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The *H. pylori* Test Device (Serum/Plasma) has been evaluated with serum and plasma specimens obtained from a population of symptomatic and asymptomatic individuals who presented for endoscopic examination.
Biopsy (Culture and/or Histology) served as the reference method for the *H. pylori* Test Device (Serum/Plasma). The specimen was considered positive if either Culture or Histology, or both, were reported positive. The specimen was considered negative if both methods were reported negative. (See Table 1)

Table 1. *H. pylori* Test Device vs. Biopsy

Method		Biopsy		Total Results
***H. pylori* Test Device**	Results	Positive	Negative	
	Positive	94	27	121
	Negative	4	85	89
Total Results		98	112	210

Relative Sensitivity: 95.9% (89.9-98.9%)*
Relative Specificity: 75.9% (66.9-83.4%)*
Accuracy: 85.2%

The discrepant specimens were resolved by ELISA for IgG antibodies to *H. pylori*. (See Table 2)

Table 2. *H. pylori* Test Device vs. Biopsy
(Resolved by ELISA)

Method		ELISA		Total Results
***H. pylori* Test Device**	Results	Positive	Negative	
	Positive	94	13	107
	Negative	0	85	85
Total Results		94	98	192

Relative Sensitivity: >99.0% (96.2-100%)*
Relative Specificity: 86.7% (78.4-92.8%)*
Accuracy: 93.2%

* 95% Confidence Intervals

Precision

Intra-Assay

Within-run precision has been determined by using 9 replicates of three specimens: a negative, a low positive and a high positive. The negative, low positive and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 27 independent assays on the same three specimens: a negative, a low positive and a high positive. Three different lots of the *H. pylori* Test Device (Serum/Plasma) have been tested using negative, low positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross-Reactivity

Sera containing known amounts of antibodies to *H. pylori* have been tested with C. jejuni, C. fetus, C. coli and E. Coli. No cross-reactivity was observed, indicating that the *H. pylori* Test Device (Serum/Plasma) has a high degree of specificity for human antibodies to *H. pylori.*

Interference Studies

The *H. pylori* Test Device (Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens, as well as specimens containing high bilirubin levels. In addition, no interference was observed in specimens containing up to 1000 mg/dL hemoglobin, up to 1000 mg/dL bilirubin, and up to 2000 mg/mL human serum albumin.

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