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INSTALERT™

H. pylori Rapid Test Device (Whole Blood/Serum/Plasma) Package Insert

English

A rapid test for the qualitative detection of antibodies to Helicobacter pylori (H. pylori) in whole blood, serum, or plasma.
For professional in vitro diagnostic use only.

INTENDED USE

The *H. pylori* Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of antibodies to *H. pylori* in whole blood, serum, or plasma to aid in the diagnosis of *H. pylori* infection in adults 18 years of age and older.

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 antibodies which correlate strongly with histologically confirmed *H. pylori* infection.[6,7,8]
The *H. pylori* Rapid Test Device (Whole Blood/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 whole blood, serum, or plasma in just minutes.

PRINCIPLE

The *H. pylori* Rapid Test Device (Whole Blood/Serum/Plasma) is a qualitative membrane based immunoassay for the detection of *H. pylori* antibodies in whole blood, serum, or plasma. In this test procedure, anti-human IgG is immobilized in the test line region of the test. After specimen is added to the specimen well of the device, it reacts with *H. pylori* antigen coated particles in the test. This mixture migrates chromatographically along the length of the test 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 will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test 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 after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing 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 being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test 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* Rapid Test Device (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum, or plasma.
- To collect **Venipuncture Whole Blood specimens**: Collect anti-coagulated blood specimen (sodium or lithium heparin, potassium or sodium EDTA, sodium oxalate, sodium citrate) following standard laboratory procedures.
- To collect **Fingerstick Whole Blood specimens**:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Add the Fingerstick Whole Blood specimen to the test by using **a capillary tube**:
    - Touch the end of the capillary tube to the blood until filled to the line. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood to the specimen well (S) of the test device.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- 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 local regulations covering the transportation of etiologic agents.

MATERIALS

Materials Provided

- Test devices
- Droppers
- Buffer
- Package insert

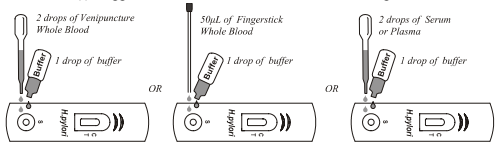
Materials Required But Not Provided

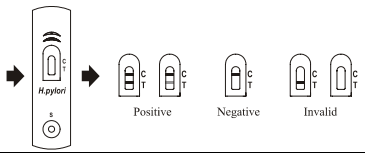
- Specimen collection containers
- Lancets (for fingerstick whole blood only)
- Centrifuge
- Timer
- Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

DIRECTIONS FOR USE

Allow the test, specimen, buffer, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface.
   For **Serum or Plasma specimens:** Hold the dropper vertically and **transfer 2 drops of serum or plasma** (approximately 50 µL) to the specimen well (S) of the test device, then add 1 drop of buffer to the specimen well (S). Start the timer. See illustration below.
   For **Venipuncture Whole Blood specimens:** Hold the dropper vertically and **transfer 2 drops of whole blood** (approximately 50 µL) to the specimen well (S) of the test device, then **add 1 drop of buffer** and start the timer. See illustration below.
   For **Fingerstick Whole Blood specimens:** Fill the capillary tube and **transfer approximately 50 µL of fingerstick whole blood** to the specimen well (S) of the test device, then **add 1 drop of buffer** and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. **Read results at 10 minutes.** Do not interpret the result after 15 minutes.





INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:* Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).
***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of *H. pylori* antibodies in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking 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* Rapid Test Device (Whole Blood/ Serum/Plasma) should be used only to evaluate patients with clinical signs and symptoms suggestive of gastrointestinal disease and is not intended for use with asymptomatic patients.
2. The *H. pylori* Rapid Test Device (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of *H. pylori* antibodies in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in *H. pylori* antibody concentration can be determined by this qualitative test.
3. The *H. pylori* Rapid Test Device (Whole Blood/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.
4. Grossly hemolysed samples will yield invalid results. Strictly follow the Package Insert instructions to obtain accurate results.
5. A positive result does not allow one to distinguish between active infection and colonization by *H. pylori*.
6. A positive result only indicates the presence of IgG antibody to *H. pylori* and does not necessarily indicate that gastrointestinal disease is present.
7. A negative result indicates that IgG antibody to *H. pylori* is not present or is below the detection limit of the test.
8. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
9. Literature references have suggested cross reactivity of IgG antibody with a closely related organism, Borrelia burgdorferi. Performance of this assay has not been evaluated with this organism. Therefore, the specificity of this test device is not known if this organism is encountered.
10. 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.
11. This assay has not been established for patients under 18 years of age.

EXPECTED VALUES

H. pylori infection is present worldwide and has been shown to correlate with age, ethnic background, family size, and socioeconomic class.[9] In the United States, the incidence of infection may increase 1-2% annually.[10] Eighty to 100% of individuals with signs and symptoms of other gastrointestinal conditions such as duodenal ulcers are reported to be positive for *H. pylori* infection.[11]

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The *H. pylori* Rapid Test Device (Whole Blood/Serum/Plasma) has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals who presented for endoscopic examination. Culture and/or Histology of biopsy specimens served as the reference method.

Of the 321 fresh clinical samples collected, 136 were considered biopsy positive and 185 clinical specimens were considered biopsy negative. Biopsy "positive" was defined as either or both culture and histology are positive and biopsy "negative" was defined as both culture and histology negative. The results for each sample matrix are summarized below.

***H. pylori* Rapid Test Device vs. Biopsy/Histology**

SERUM

Method		Biopsy/Histology	
	Results	Positive	Negative
***H. pylori* Test Device**	Positive	121	21
	Negative	15	164

Sensitivity = 121/136 = 89% (82%-94%)* Specificity = 164/185 = 89% (83%-93%)*
Accuracy = 285/321 = 89% (85%-92%)*

PLASMA

Method		Biopsy/Histology	
	Results	Positive	Negative
***H. pylori* Test Device**	Positive	120	21
	Negative	16	164

Sensitivity = 120/136 = 88% (81%-93%)* Specificity = 164/185 = 89% (83%-93%)*
Accuracy = 284/321 = 88% (84%-92%)*

FINGERSTICK

Method		Biopsy/Histology	
	Results	Positive	Negative
***H. pylori* Test Device**	Positive	54	12
	Negative	8	76

Sensitivity = 54/62 = 87% (76%-94%)* Specificity = 76/88 = 86% (77%-93%)*
Accuracy = 130/150 = 87% (80%-92%)*

VENOUS WHOLE BLOOD

Method		Biopsy/Histology	
	Results	Positive	Negative
***H. pylori* Test Device**	Positive	119	22
	Negative	17	163

Sensitivity = 119/136 = 88% (81%-93%)* Specificity = 163/185 = 88% (83%-92%)*
Accuracy = 282/321 = 88% (84%-91%)* *Denotes 95% Confidence Interval

POL Studies

Three physicians' offices were used to conduct an evaluation of the *H. pylori* Rapid Test Device (Whole Blood/Serum/Plasma). Personnel with various educational backgrounds performed the testing. Each physician's office tested a randomly coded panel of samples consisting of negative (20), low positive (20) and medium positive (20) for three days. The results obtained had a >99% correlation with the expected results.

Cross-Reactivity

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

Interference Studies

No interference with the *H. pylori* Rapid Test Device (Whole Blood/Serum/ Plasma) results was observed in samples containing high levels of hemoglobin (up to 1000 mg/dL), bilirubin (up to 1000 mg/dL) and human serum albumin (up to 2000 mg/mL). The test results were also unaffected when the hematocrit was altered ranging from 20% to 67%. 600mg/dL triglyceride concentration sample did not interfere with test performance.

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Index of Symbols

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #

Manufacturer

Innovacon, Inc.
9975 Summers Ridge Road
San Diego, CA 92121, USA

CE

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany