Rapid Response®

***H.pylori* Test Strip**
(Whole Blood/Serum/Plasma)

REF HPY-13S50 Product Insert

For professional *in vitro* diagnostic use only.

Intended Use

The Rapid Response® *H. pylori* Test Strip is a rapid visual immunoassay for the qualitative presumptive detection of specific IgG antibodies to Helicobacter pylori in human whole blood, serum, or plasma specimens. This kit is intended for use as an aid in the diagnosis of *H. pylori* infection.

Introduction

Gastritis and peptic ulcers are among the most common human diseases. Since the discovery of *H. pylori* (Warren & Marshall, 1983), many reports have suggested that this organism is one of the major causes of ulcer diseases (Anderson & Nielsen, 1983; Hunt & Mohamed, 1995; Lambert et al, 1995). Although the exact role of *H. pylori* is not yet fully understood, eradication of *H. pylori* has been associated with the elimination of ulcer diseases. The human serological responses to infection with *H. pylori* have been demonstrated (Varia & Holton, 1989; Evans et al, 1989). The detection of IgG antibodies specific to *H. pylori* has been shown to be an accurate method for detecting *H. pylori* infection in symptomatic patients. *H. pylori* may colonize some asymptomatic people. A serological test may be used either as an adjunct to endoscopy or as an alternative measure in symptomatic patients.

Principle

The Rapid Response® *H. pylori* Test Strip detects IgG antibodies specific to Helicobacter pylori through visual interpretation of colour development on the internal strip. Anti Human IgG is immobilized on the test region of the membrane. During testing, the specimen reacts with *H. pylori* antigen conjugated to coloured particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there are sufficient antibodies to Helicobacter pylori in the specimen, a coloured band will form at the test region of the membrane. The presence of this coloured band indicates a positive result, while its absence indicates a negative result. The appearance of a coloured band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

Precautions

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the 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 results.
- Used testing materials should be discarded according to local regulations.

Materials

Materials provided

- Individually packed test strips
- Disposable pipettes
- Buffer
- Product insert

Materials required but not provided

- Specimen collection container
- Centrifuge
- Timer

Storage and Stability

- The kit should be stored at 35.6-86°F (2-30°C) until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

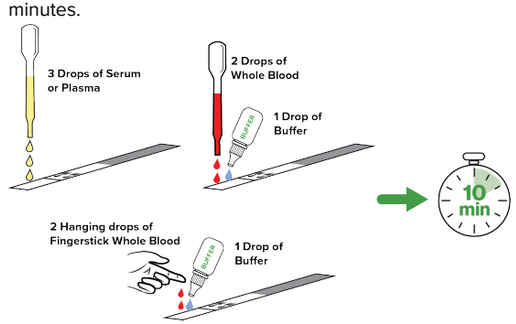
Collection and Storage of Specimens

- The Rapid Response® *H. pylori* Test Strip is intended for use with human whole blood, serum, or plasma specimens only.
- Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated as soon as possible to avoid hemolysis.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 35.6-46.4°F (2-8°C) for up to 7 days. For long term storage, specimens should be kept below -4°F (-20°C). Whole blood collected by venipuncture should be stored at 35.6-46.4°F (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.
- Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
- Icteric, lipemic, hemolysed, heat treated and contaminated specimens may cause erroneous results.

Test Procedure

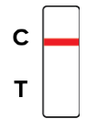
Bring tests, specimens, buffer and/or controls to room temperature (59-86°F; 15-30°C) before use.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the Strip with patient or control identification. For best results the assay should be performed within one hour.
2. Transfer 3 drops of serum or plasma (approximately 75 µL) to the sample pad with the strip with the provided disposable pipette and start the timer.
   OR
   Transfer 2 drop of whole blood specimen (approximately 50 µL) to the sample pad with the provided disposable pipette, then add 1 drop of buffer and start the timer.
   OR
   Allow 2 hanging drops of fingerstick whole blood specimen to fall into the center of the sample pad on the strip, then add 1 drop of buffer and start the timer.
   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.
   As the test begins to work, colour will migrate across the result area in the center of the device.
3. Wait for the coloured band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

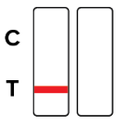


Results Interpretation

POSITIVE: Two coloured bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).



NEGATIVE: Only one coloured band appears, in the control region (C). No apparent coloured band appears in the test region (T).



INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of colour in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of colour in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

Quality Control

- Internal procedural controls are included in the test. A coloured band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. 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 Rapid Response® *H. pylori* Test Strip is for professional in vitro diagnostic use, and should only be used for the qualitative detection of *H. pylori* antibodies. No meaning should be inferred from the colour intensity or width of any apparent bands.
2. This test should be used for symptomatic individuals with gastrointestinal disorders. Diagnosis of gastritis and/or peptic ulcers should be based on test results in conjunction with other clinical and laboratory findings.

3. A positive result suggests only the presence of antibodies specific to *H. pylori*, and does not distinguish between active and past infections. A positive result is not necessarily indicative of gastrointestinal disease.
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 rule out the possibility of *H. pylori* infection, as antibodies to *H. pylori* may be present below the minimum detection level of the test.
5. Specimens from patients infected with C. jejuni may exhibit a low level of cross-reactivity in this test.

Performance Characteristics

Table: *Rapid Response® H. pylori Test Strip* vs. Biopsy/Histology/RUT

Relative Sensitivity: 93.2% (89.5%-95.6%)*
Relative Specificity: 97.2% (94.9%-98.5%)*
Overall Agreement: 95.5% (93.5%-96.8%)*
*95% Confidence Interval

		Rapid Response® *H. pylori* Test Strip		
		+	-	Total
Biopsy/ Histology/ RUT	+	246	18	264
	-	10	343	353
		256	361	617

Bibliography

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Glossary of Symbols

Consult instructions for use	Test per Kit	Do Not Reuse
Store between 35.6°F to 86°F	Use by	Catalogue #
Lot Number	For *in vitro* diagnostic use only	Do Not Reuse

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