BTNX INC.

Rapid Response®

***H. Pylori* Test Cassette**
(Whole Blood/Serum/Plasma)

REF HPY-13C15, HPY-13C25, HPY-13C40, HPY-13C

Product Insert

A rapid test for the qualitative detection of antibodies to *Helicobacter pylori (H. pylori)* in whole blood, serum or plasma.

For professional laboratory *in vitro* diagnostic use only.

Intended Use

The Rapid Response® *H. pylori* Test Cassette 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.

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 Rapid Response® *H. pylori* Test Cassette 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.

Principle

The Rapid Response® *H. pylori* Test Cassette 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.

Materials

Materials provided

- Test cassettes
- Droppers
- Positive control
- Buffer
- Product insert
- Negative control

Materials required but not provided

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

Storage and Stability

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C; 35.6-86°F). 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.

Collection and Storage of Specimens

- The Rapid Response® *H. pylori* Test Cassette can be performed using whole blood (from venipuncture or fingerstick) serum or plasma.
- 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 approximately 75 µL. 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 area of the test cassette.
  - Add the Fingerstick Whole Blood specimen to the test by using **hanging drops:**
    - Position the patient's finger so that the drop of blood is just above the specimen area of the test cassette.
    - Allow 3 hanging drops of fingerstick whole blood to fall into the center of the specimen area on the test cassette, or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
- 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 the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C (35.6°F) for up to 3 days. For long term storage, specimens should be kept below -20°C (-4°F). Whole blood collected by venipuncture should be stored at 2-8°C (35.6°F) 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.

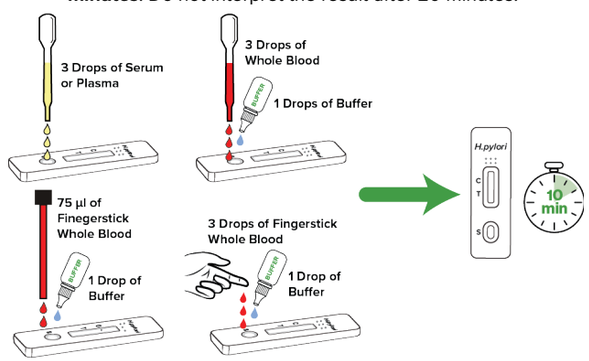
Test Procedure

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C; 59-86°F) prior to testing.

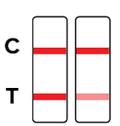
1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface.
   For Serum or Plasma specimen:
   - Hold the dropper vertically and transfer **3 drops of serum or plasma** (approximately 75 µL) to the specimen well of test Cassette and start the timer. See illustration below.

   For Venipuncture Whole Blood specimen:
   - Hold the dropper vertically and transfer **3 drops of whole blood** (approximately 75 µL) to the specimen well, then **add 1 drop of buffer** (approximately 40 µL), and start the timer. See illustration below.

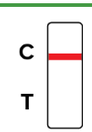
   For Fingerstick Whole Blood specimen:
   - To use a capillary tube: Fill the capillary tube and **transfer approximately 75µL of fingerstick whole blood specimen** to the specimen area of test cassette, then **add 1 drop of buffer** (approximately 40 µL) and start the timer. See illustration below.
   - To use hanging drops: Allow **3 hanging drops of fingerstick whole blood specimen** (approximately 75 µL) to fall into the specimen area of test cassette, then **add 1 drop of buffer** (approximately 40 µL) 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 20 minutes.



Results Interpretation



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



NEGATIVE: One colored line appears in the control region (C). No colored line appears in the test region (T).

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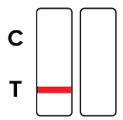

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact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

Quality Control

A procedural control is included in the test. A colored 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 Rapid Response® *H. pylori* Test Cassette 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.
2. The Rapid Response® *H. pylori* Test Cassette 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.

Performance Characteristics

Clinical Sensitivity, Specificity and Accuracy

The Rapid Response® *H. pylori* Test Cassette has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals who presented for endoscopic examination. Biopsy (Culture) served as the reference method for the Rapid Response® *H. pylori* Test Cassette. Histology and a Rapid Urease Test (RUT) were performed on all negative culture specimens. The specimen was considered positive if Culture was positive. The specimen was also considered positive if the Culture was negative, but both Histology and RUT were positive. The result shows that the sensitivity of the Rapid Response® *H. pylori* Test Cassette is 96.8% and the specificity is 93.0% relative to Biopsy/Histology/RUT.

Rapid Response® *H. pylori* Test Cassette vs. Biopsy/Histology/RUT Method

Method		Biopsy/Histology/RUT		Total Results
Rapid Response® *H. pylori* Test Cassette	Results	Positive	Negative	
	Positive	150	15	165
	Negative	5	200	205
Total Results		155	215	370

Relative Sensitivity: 96.8% (95%CI*: 92.6%-98.9%)
Relatively Specificity: 93.0% (95%CI*: 88.8%-96.0%)
Accuracy: 94.6% (95%CI*: 91.8%-96.7%)
*Confidence Interval

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of the Rapid Response® *H. pylori* Test Cassette have been tested using negative, low positive, medium 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 Hepatitis A, B, C, E, HIV and Syphilis. No cross-reactivity was observed, indicating that the Rapid Response® *H. pylori* Test Cassette has a high degree of specificity for antibodies to *H. pylori*.

Interfering Substances

The Rapid Response® *H. pylori* Test Cassette has been tested for possible interference from visibly hemolyzed and lipemic specimens, as well as serum specimens containing high bilirubin levels. In addition, no interference was observed in specimens containing up to 1,000 mg/dL hemoglobin; up to 1,000 mg/dL bilirubin; and up to 2,000 mg/dL human serum albumin.

Bibliography

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Glossary of Symbols

Consult instructions for use	Test per Kit	EC REP Authorized Representative	
2°C 30°C Store between 2°C to 30°C (35.6°F to 86°F)	Use by	Do Not Reuse	
LOT Lot Number	IVD For *in vitro* diagnostic use only	REF Catalogue #	
Manufacturer			

EC REP
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CE

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