QUANTON BIOLIFE SCIENCES

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H. Pylori Ab Rapid Test Kit (Serum/Plasma/Whole blood)

QBL/HPy/RPT_39

The H. Pylori Ab Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of H. Pylori Antibodies (IgG, IgM and IgA) in human serum/plasma/whole blood specimens.

For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
01 Test	PHPB 01
05 Tests	PHPB 05
10 Tests	PHPB 10
25 Tests	PHPB 25
50 Tests	PHPB 50

CLINICAL SIGNIFICANCE

Helicobacter pylori is associated with a variety of gastrointestinal diseases including non-ulcer dyspepsia, duodenal and gastric ulcers and active, chronic gastritis[1,2]. The prevalence of H. pylori infection could exceed 90% in patients with signs and symptoms of gastrointestinal diseases. Recent studies indicate an association of H. pylori infection with stomach cancer[3]. H. pylori colonizing in the gastrointestinal system elicits specific antibody responses[4,5] which aid in the diagnosis of H. pylori infections and in monitoring the effectiveness of treatment for H. pylori related diseases. Successful eradication of H. pylori is associated with clinical improvement in patients with gastrointestinal diseases providing further evidence

H.pylori Ab Rapid Test is the latest generation of chromatographic immunoassays which utilizes recombinant antigens to detect antibodies to H. pylori in human serum, plasma or whole blood. The test is user friendly, highly sensitive and specific.

PRINCIPLE

H. pylori Ab Combo Rapid Test is a lateral flow chromatographic immunoassay based on the principle of the double-antigen sandwich technique. The test cassette consists of: 1) a colored conjugate pad containing H. pylori antigens including Cag-A conjugated with colloidal gold (H. pylori conjugates) and a control antibody conjugated with colloidal gold, and 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with non-conjugated H. pylori antigens, and the C line is pre-coated with a control line antibody.
When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. Antibodies (IgG, IgM or IgA) to H. pylori, if present in the specimen, will bind to the H. pylori conjugates. The immunocomplex is then captured on the membrane by the pre-coated H. pylori antigens forming a colored T line, indicating a H. pylori Ab positive test result. Absence of the T line suggests a negative result. The test contains an internal control (C line) which should exhibit a colored line of the immunocomplex of the control antibodies regardless of color development on the T line. If the C line does not develop, the test result is invalid, and the specimen must be retested with another device.

KIT COMPONENTS

• Test Cassettes • Droppers • Buffer • Package Insert • Alcohol Swab
• Lancet (for fingerstick whole blood only)

MATERIALS REQUIRED BUT NOT PROVIDED

• Specimen Collection Containers • Centrifuge (For plasma only) • Timer

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore, take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mention in the insert.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION

The H. Pylori Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum and plasma specimen.

- **Serum (S):** Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by veinpuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
- **Plasma (P):** Collect the whole blood into a collection tube (containing anticoagulants such as EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium) by veinpuncture and then centrifuge blood to get plasma specimen.
- **Whole Blood (WB):** Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.

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 sample well of the test cassette by using a sample dropper. Avoid air bubbles.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. For long term storage, specimens should be kept below -20°C. 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.

DIRECTIONS FOR USE

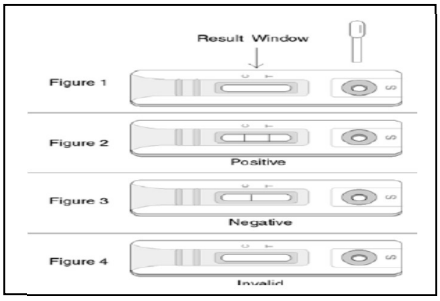
Allow the test device, specimen and/or buffer to equilibrate at room temperature (15-30°C) before testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within 1 hour.
2. Place the cassette on a clean and level surface.
3. **For Serum or Plasma specimen**: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 10µL) and add 2 drop of buffer (approximately 80 µL) into the specimen well, and start the timer. See illustration below.
   For Venipuncture Whole Blood specimen: Hold the dropper vertically and transfer 1 drop of whole blood (approximately 10 µl) to the specimen well, then add 2 drop of buffer (approximately 80 µL), and start the timer. See illustration below.

For Fingerstick Whole Blood specimen: Take sample using sample dropper and transfer approximately 10 µL (1 drop) of fingerstick whole blood specimen to the specimen well of test cassette, then add 2 drop of buffer (approximately 80 µL) and start the timer. See illustration below.

4. Wait for the colored line(s) to appear. Read results at 5 minutes.
Note: Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS



1) Positive
The control line (C) and test line (T) lines are visible on the test device. This is positive for H. Pylori Ab. This is indicative of presence of H. Pylori infection
2) Negative
The control line is the only visible line on the test device. No H.Pylori Ab were detected
3) Invalid
The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the likeliest reasons for control line failure. Repeat the test using a new test device.

Quality Control

Internal procedural controls are included in the test individually. A colored line appearing in control line 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 of the Test

1. The H. Pylori Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of H. Pylori Ab in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of H. Pylori Ab can be determined by this qualitative test.
2. A negative result can occur if the level of H. Pylori Ab present in the specimen is below the detection limits of the assay H.Pylori Ab that is detected is not present during the stage of H.Pylori infection in which a sample is collected. However, a negative test result does not preclude the possibility of H. Pylori infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

Sensitivity and Specificity
A total of 275 specimens were collected (including susceptible subjects) and tested by H. pylori Ab Rapid Test and a commercial Troponin-I Rapid test as reference. Comparison for all subjects is showed in the following table.

Method		Other Rapid Test		Total Test
H.Pylori Ab Rapid Card Test	Result	Positive	Negative	
	Positive	73	2	75
	Negative	2	198	200
Total Results		75	200	275

Relative Sensitivity: 97.3% (95% CI: 97.8-98.9%) Relative Specificity: 99% (95% CI: 98.8-99.9%) Overall Agreement: 98.54% (95% CI: 98.8-99.9%)

Cross-reactivity
The H.Pylori Ab Rapid Test Cassette (Serum/Plasma/Whole Blood) has been tested for HBsAg, anti-HIV, anti-HCV, anti-RF, anti-Spyhilis, anti-Toxo IgG positive specimens. The results showed no cross-reactivity.

Interfering Substances
The following compounds have also been tested using the H.Pylori Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed. Caffeine: 20mg/dl, Creatine: 200mg/dl, Acetylsalicylic Acid: 20mg/dl, Gentisic Acid: 20mg/dl, Albumin: 2000mg/dl, Ascorbic Acid: 2g/dl, Hemoglobin: 1000mg/dl, Oxalic acid: 600mg/dl, Bilirubin: 1000mg/dL, Triglycerides: 1600mg/dl & Cholesterol: 800mg/d.l

BIBLIOGRAPHY

1. Marshall, B.J., McGechie, D.B., Rogers, P.A.R., et.al. Pyloric Campylobacter infection and gastroduodenal disease. Med. J. Australia. 1985.149:439-44
2. Soll, A.H. Pathogenesis of peptic ulcer and implication for therapy. New England J. Med.1990.322:909-16.
3. Parsonnet, J., Friedman, G.D., Vandersteen, D.P., et.al. Helicobacter pylori infection and risk of gastric carcinoma. New England J. Med. 1991.325:1127-31.
4. Ansorg, R., Von Recklinghausen, G., Pomarius, R., et.al. Evaluation of techniques for isolation, subcultivation and preservation of Helicobecter pylori. J. Clin. Micro. 1991.29:51-3.
5. Pronovost, A.P., Rose, S.L., Pawlak, J., et.al. Evaluation of new immunodiagnostic assay for Helicobacter pylori antibody detection: Correlation with histopathological and microbiological results. J. Clin. Microbiol.1994.32:46-50

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer	IVD	For *in vitro* Diagnostic use only
	Keep away from sunlight	CONT	Content of the kit
Σ	Tests per Kit		Do Not Use if Damaged
	Do not reuse		Keep Dry

Paramcare Life Sciences Private Limited, G/F-12/13, Evershine-2, Survey No. 307/3/1, Balitha N.H No 48, Vapi, Valsad, Gujarat, 396191.

Quanton Biolife Sciences Private Limited
Anand Mangal Apartment, Behind Axis Bank,
Dak Bunglow Road, Ghatsila, East Singhbhum
Jharkhand – 832303, India
quantoncare@qblsci.com, www.quantonbiolifesciences.com