ASTAM DIAGNOSTICS

PRODUCT INSERT

REF HPBD

PRATHAM® H. PYLORI ANTIBODY TEST

A lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG/IgM and IgA) against H. pylori in human serum / plasma / whole blood.

INTENDED USE

PRATHAM® H. pylori Test is a rapid, qualitative, sandwich immunoassay for simultaneous detection of total antibodies (IgM / IgG / IgA) to H. pylori in human serum / plasma / whole blood. For professional use only.

INTRODUCTION

PRATHAM® H. pylori Test 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. 6,7,7 The H. pylori Rapid Test Device (Whole Blood / Serum / Plasma) is a sample 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 inn just minutes.

TEST PRINCIPAL

PRATHAM® H. pylori Test utilizes the principle of Immunochromatography, a unique two-site immunoassay on a nitrocellulose membrane. Highly purified antigen of H. pylori (CagA) is coated on the nitrocellulose membrane as test line. An assay control reagent (Goat anti rabbit IgG) forms the second band. Corresponding antigen (CagA) and rabbit IgG are conjugated to colloidal gold. When the test is performed, the highly specific CagA antigen-colloidal gold conjugate complexes with H. pylori specific antibodies in the specimen and travels on the membrane due to capillary action along with the rabbit IgG-colloidal gold conjugate. The complex moves further on the membrane to the test line region, where it is immobilized by the H. pylori antigen coated on the membrane at test line, this leads to the formation of colored band. The presence of colored band in the test regions indicates the presence of antibodies to H. pylori in the specimen. The inreacted conjugate and unbound complex, if any, along with rabbit IgG gold conjugate moves further on the membrane and are subsequently immobilized forming a colored band. This control band acts as an internal control and serves to validate the results.

KIT COMPONENTS

1. Pouch contents: Test Cassette, Sample Dropper, Desiccant
2. Assay Buffer
3. Instruction for use

MATERIAL REQUIRED BUT NOT PROVIDED

Timer, Gloves, Micropipette, tips & centrifuge etc.

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 2-30ºC till the duration of self life as indicated on the pouch. Do not freeze. Once the pouch is opened, test card must be used immediately.

SPECIMEN COLLECTION AND STORAGE

1. No prior preparation of the patient is required.
2. Collect blood specimen by venipuncture according to the standard procedure.
3. Specimen (serum / plasma / whole blood) should be free of particulate matter and microbial contamination.
4. Preferably use fresh sample. However, specimen can be stored refrigerated for short duration. For long storage, freeze at -20ºC or below. Do not freeze whole blood sample. Specimen should not be frozen and thawed repeatedly.

5. Do not heat inactivate before use.
6. Turbid sample (microbial contamination) should not be used.
7. Specimens containing precipitate or particulate matter should be centrifuged prior to use.

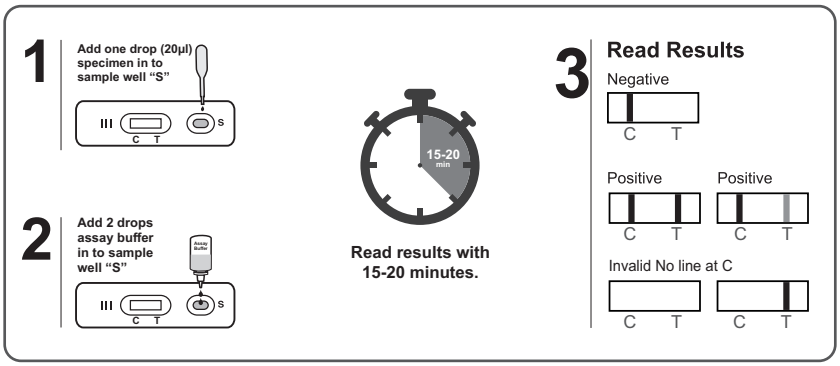
WARNING AND PRECAUTIONS

- Use product insert to perform the assay.
- Failure to follow the insert gives inaccurate test results.
- Do not use expired kit.
- Use separate sample collection tube or micro pipette tips for each sample to avoid cross contamination.
- Do not use hemolized blood specimens for testing.
- Do not throw away used device, sample tube and tips any were discard it in proper way as bio hazardous waste.
- Use of disposable gloves and bio-hazardous clothing while running the test.
- The test shall be performed by competent person only.
- Bring all reagents and specimen to room temperature before use.
- Spills should be decontaminated promptly with IPA or any other suitable disinfectant.
- Do not unwrap the packed until it attains room temperature.
- Do not re-use the test device.

TEST PROCEDURE

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. Check the packaging is not damaged. If damaged, discard the test and use another test.
3. Open the pouch & check the desiccant. If color of desiccant does not show any change (Remains blue) you can use the test. If color changes then discard the test and use another test.
4. Add one drop (20µl) of serum /plasma/whole blood into the sample well.
5. Add 2 drops of assay/running buffer into the sample well using provided buffer vial.
6. Interpret test results within 15-20 minutes. Don't interpret results after 20 minutes.

INTERPRETATION OF RESULTS



Negative:

Appearance of only pink / purple line at control line region 'C' and No pink / purple line at test line region 'T' of the result window, indicates that specimen has no indicates presence of antibody of H. pylori and result is negative.

Positive:

Appearance of two pink / purple lines, one at test region 'T' and other at control line region 'C' of the result window, indicates that specimen has indicates presence of antibody of H. pylori and result is positive.

Invalid:

If there is no pink / purple line in the control line region 'C' of the result window, the result is invalid. This is due to deterioration of the test device or improper test procedure. Repeat the test a new test device.

INTERNAL QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control region 'C' is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. External controls are not supplied with this kit. It is recommended that positive and negative controls should be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Handle the negative and positive controls in the same manner as patient specimens.

PERFORMANCE CHARACTERISTICS

Based on internal evaluation:

1. Sensitivity of H. pylori test: ≥ 92%
2. Specificity of H. pylori test: ≥ 85.5%

LIMITATION OF THE TEST

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 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 haemolysed 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 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 reactively 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

The majority of individuals exposed to H. pylori possess antibodies against H. pylori. It is reported that H. pylori is universally distributed and as estimated value 50% of the world's populations are colonized by H. pylori (Lambert et al., 1995). The presence of H. pylori antibodies is a function of age, race, geography and clinical condition. A relatively large proportion of patients who have positive levels of antibodies are without any symptoms, even though they are colonized with the H. pylori. Therefore, antibody levels do not necessarily correlate with the severity of clinical symptoms (Tytgat & amp; Rauws, 1989).

DISPOSAL

Consider all test devices run with human specimen as potentially infectious and discard using standard biosafety practices.

DISCLAIMER:

Every precaution has been taken to ensure diagnostic ability and accuracy of this product. This product is used outside the control of manufacturer and distributors. Various factors including storage temperature, environment conditions, and procedural errors may affect the result. A person who is subject of the diagnosis should consult a doctor for further confirmation.

WARNING

The Manufacturer and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative in the use of this product.

BIBLIOGRAPHY OF SUGGESTED READING

1. Marshall, B.J. et. al. 1985. Med. J. Australia. 149:439-44.
2. Soll, A.H. 1990. New England J. Med. 322:909-916.
3. Parsonnet, J. et. al. 1991. New England J. Med. 325:1127-31.
4. Ansong, R. et. at. 1991. J. Clin. Microbiol. 32:51-53.

5. Pronovost, A.P. et. al. 1994. J. Clin. Microbiol. 32:46-50.
6. Megraud, F. et. al. 1989. 27:1870-3, 1989.
7. Marshall, B.J. et. al. 1988. Lancet. Dec. 1437-42.

SYMBOLS

Read instructions for use	Name of Manufacturer	For single use only
No. of test	Expiry Date of Kit.	Date of manufacturing of IVD Kit
IVD In-vitro diagnostic use	Keep away from Sunlight	REF Reference Catalogue Number
Storage Condition		

ASTAM DIAGNOSTICS

Manufactured By:
ASTAM DIAGNOSTICS PVT. LTD.
Plot No. H-125, RIICO Indl. Area, Kaharani, Bhiwadi Extn.
Alwar, Rajasthan-301019 (INDIA)
For feedback/queries contact customer care : 011-27358101