ASTAM DIAGNOSTICS

PRODUCT INSERT

REF HPAD

PRATHAM®
H.Pylori Antigen

INTENDED USE

PRATHAM® H.Pylori Antigen Test is a rapid immunoassay based upon chromatography principle for the qualitative detedtion of H. Pylori Ag present in the feces by using specific antibodies, which indicates an actiove H.pylori infection. For professional and in-vitro diagnostic use only.

INTRODUCTION

H.pylori is a small, spiral-shaped bacterium that lives in the surface of the stomach andduodenum. It is implecated in the etiology of a variety of gastrointestianl diseases, including duodenal and gastriculcer, nonulcer dyspepsia and acitve and chronic gastritis. 1,2 Both invasive and non-invasive methods are used todiagnose 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 techiniques include the urea breath test, which requires expensive laboratory equipment and moderate radiation exposure, and serological methods. 4,5 Individuals infection 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.

TEST PRINCIPAL

PRATHAM® H.pylori Antigen Test reacts with the conjugate-Red latex sensibilize with anti-H.pylori monoclonal antibody coated to the membrane of the test. The formed H.pylori conjugate complex, which migrates upward the membrane by capillarity, binds to the specific antibody molecules fixed to the reaction zone. The excess of complex keeps migrating through the membrane until reaching the C zone of control, where will bind to another specific antibody coated to the membrane forming a green band. The green band presence confirms the functionality of the test.

KIT COMPONENTS

1. Individually sealed foil pouches containing: A. one cassette device B. One desiccant
2. Stool collection devices, each containing Sample Extraction Buffer.
3. Plastic droppers for transferring watery stool.
4. One package insert (instruction for use).

MATERIAL REQUIRED BUT NOT PROVIDED

Timer, Gloves, Micro Pipette, Tips & Centrifuge etc.

STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 2-40ºC till the duration of shelf life as indicated on the pouch. Do not freeze. Once the pouch is opened, test card must be used immediately.

SPECIMEN COLLECTION AND HANDLING

1. Stool: Do not use watery or diarrhoeal samples.
2. Collect the stool sample in a clean container and use as soon as possible.
3. The samples can be stored at 2-8ºC for a longer period of time.

WARNING AND PRECAUTIONS

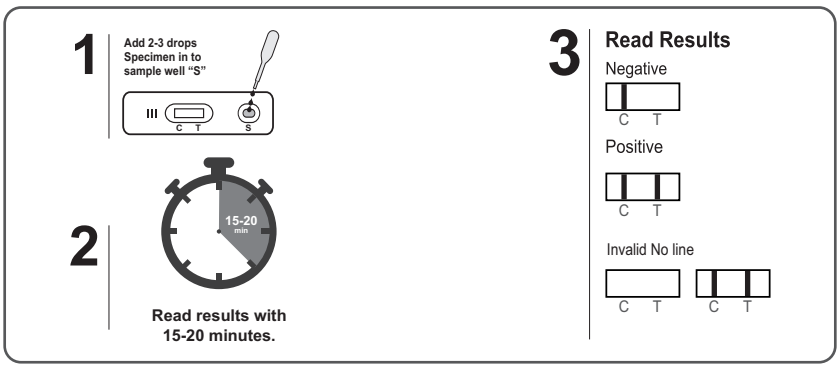
1. For professional use only, not to be used by the general public.
2. The test must be carried out by or under the direction of a registered medical practitioner or by a technician at the request of registered medical practitioner.
3. Bring all reagents and specimen to room temperature before use.

4. Do not pipette any material by mouth.
5. Do not eat, drink or smoke in the area where testing is done.
6. Use protective clothing and wear gloves when handling samples.
7. Use absorbent sheet to cover the working area.
8. Immediately clean up any spills with sodium hypochlorite.
9. Dispose off all the reagents and material used as if they contain infectious agent.
10. Neutralize acid containing waste before adding hypochlorite.
11. Do not use kit after the expiry date.
12. Do not mix components of one kit with another
13. Sample running buffer contains sodium azide (0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build-up in the plumbing.

TEST PROCEDURE

1. Bring the specimen and test components to room temperature Once the specimen is thawed, mix well prior to performing the assay.
2. When ready to test, open the pouch at the notch and remove the test device. Place the test device on a clean, flat surface.
3. Shake the stool collection device vigorously to ensure a homogenous liquid suspension.
4. Insert the stool specimen with the help of dropper into the Assay buffer tube and mix it.
5. Dispense 2-3 drops of the solution (containing stool specimen) with the help of dropper into the sample well of the cassette. Do not overload the solution.
6. Read the result in 15-20 minutes.

INTERPRETATION OF RESULTS



Positive:
Two colored lines appear. Both T (Test) line and C (Control) line appear. This result means that there is the presence of the H. pylori antigen in feces and that you should consult a physician.

Note:
The intensity of the color in the test line region (T) will vary depending on the concentration of H. pylori antigen present 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). This result means that the presence of the H. pylori antigen in feces was not detectable.

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.

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

Pratham® H.pylori Antigen Test has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. The result shows that the sensitivity of the H. pylori Antigen Rapid Test is 97.6% and the specificity is 97.9% relative to other rapid test.

LIMITATION OF THE TEST

1. The test mus be carried out immediately after opening the dealed bag.
2. The cilnical diagnosis must not be done with the result of an loy assay, the clinical background of the patient must also be taken in account.

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.

BIBLOGRAPHY OF SUGGESTED READING

1. Marshall, BJ, McGechie, DB, Rogers, PAR and Glancy, RG. Pyloric Campylobacter infection and gastroduodenal disease. Med. J. Australia. (1985), 149: 439-444.
2. Soll, AH. Pathogenesis of peptic ulcer and implications for therapy. New England J.Med.(1990), 322: 909-916.
3. Hazell, SL, et al. Campylobacter pylori is and gastritis I: Detection of urease as a marker of bacterial colonization and gastritis. Amer. J. Gastroenterology. (1987), 82
4. 292-296. 4. Cutler AF. Testing for Helicobacter pylori in clinical practice. Am j. Med. 1996; 100:35S-41S.
5. Anand BS, Raed AK, Malaty HM, et al. Loe point prevalence of peptic ulcer in normal individual with Helicobacter pylori infection. Am J Gastroenterol. 1996,91:1112-1115.

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		

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

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