PreventID® **H. pylori Antigen**

Manual (FOR PROFESSIONAL USE)

REF KSTIHP602G10

Intended Use

The **PreventID® H. pylori Antigen** is a rapid chromatographic immunoassay for the qualitative detection of *H. pylori* antigens in human faeces specimens to aid in the diagnosis of *H. pylori* infection.

Introduction

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] A very common approach to the diagnosis of *H. pylori* infection is the serological identification of specific antibodies in infected patients. The main limitation of serology test is the inability to distinguish current and past infections. Antibodies may be present in the patient's serum long after eradication of the organisms.[4] HpSA (*H. pylori* Stool Antigen) testing is gaining popularity for diagnosis of *H. pylori* infection and also for monitoring the efficacy of the treatment of *H. pylori* infection. Studies have found that more than 90 % of patients with duodenal ulcer and 80 % of patients with gastric ulcer are infected with H. pylori.[5] The **PreventID® H. pylori Antigen** test utilises antibodies specific for *H. pylori* antigens to selectively detect *H. pylori* antigens in human faeces specimens.

Test Principle

The **PreventID® H. pylori Antigen** is a qualitative, lateral flow immunoassay for the detection of *H. pylori* antigens in human faeces specimens. In this test, the membrane is pre-coated with anti-*H. pylori* antibodies on the test line region of the test. During testing, the specimen reacts with the particle coated with anti-*H. pylori* antibodies. The mixture migrates upward on the membrane by capillary action to react with anti-*H. pylori* antibodies on the membrane and generate a coloured line. The presence of this coloured line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a coloured line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

The test device contains monoclonal anti-*H. pylori* antibodies coated particles and monoclonal anti-*H. pylori* antibodies coated on the membrane.

Materials

Materials Provided

- test devices, individually packed TEST
- sample collection tubes with extraction buffer TUBE
- manual

Material Required but not Provided: Specimen collection containers, pipette and disposable tips (optional), centrifuge, droppers, timer or stop watch

Storage and Stability

The kit can be stored at room temperature or refrigerated (2–30°C). The test device is stable through the expiry date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **Do not freeze**. Do not use beyond the expiry date.

Precautions

1. For *in vitro* diagnostic use only.
2. Do not eat or smoke while handling specimen. Wear protective gloves and wash hands thoroughly after performing the test.
3. Avoid splashing or aerosol formation while handling specimen and performing the test.
4. All faecal samples and materials used should be treated as potentially infectious and disposed in a biohazard container. Clean all contaminated objects and surfaces carefully.
5. Do not use test if the pouch is torn or if the membrane of the test device is visibly damaged.
6. Humidity and temperature can adversely affect results.
7. Read the instruction carefully before performing the test.
8. Do not mix reagents from different lots.
9. If you have any questions please contact Preventis GmbH.

Sample Collection and Test Procedure

The faeces specimen must be collected in clean, dry, waterproof container containing no detergents, preservatives or transport media. Bring the necessary reagents to room temperature before use. If specimen are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

Allow the test device, specimen, and sample collection tube (with extraction buffer) to reach room temperature (15–30 °C) prior to testing.

1. To collect faecal specimens:
   Collect sufficient quantity of faeces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Specimen collected may be stored for 3 days at 2–8 °C if not tested within 6 hours. For long term storage, specimens should be kept below -20 °C.
2. To process faecal specimens:
   <u>For Solid Specimens</u>:
   Unscrew the green cap of the sample collection tube; then randomly stab the attached sample collection stick into the faecal specimen in at least 3 different sites to collect approximately 50 mg of faeces (equivalent to 1/4 of a pea). Do not scoop the faecal specimen.
   <u>For Liquid Specimens</u>:
   Hold the dropper vertically, aspirate faecal specimens, and then transfer 2 drops (approximately 80 µL) into the sample collection tube containing the extraction buffer.

   Tighten the green cap onto the sample collection tube, then shake the sample collection tube vigorously to mix the specimen and the extraction buffer. Leave the tube for 2 minutes.

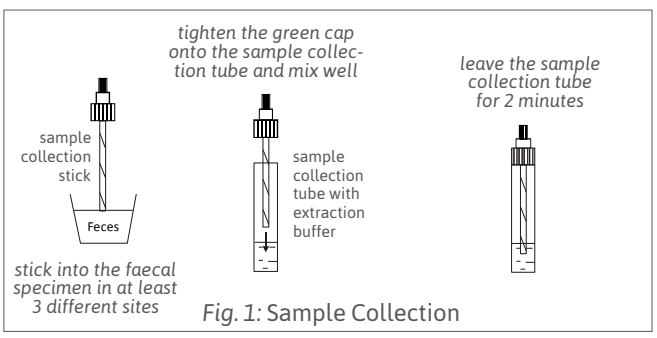

Fig. 1: Sample Collection

3. Bring the pouch to room temperature before opening it. Remove the test device from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
4. Hold the sample collection tube upright and open the small transparent cap of the sample collection tube. Invert the sample collection tube and transfer **2 full drops of the extracted specimen** (approximately 80 µL) to the sample application window (S) of the test device (*Fig. 2*), then start the timer. Avoid trapping air bubbles in the sample application window.

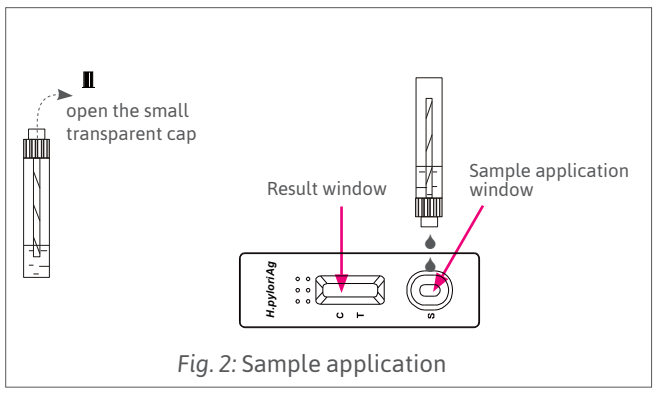

Fig. 2: Sample application

5. Read results at **10 minutes** after dispensing the specimen. Do not read results after 20 minutes.

Note: If the specimen does not migrate (presence of particles), centrifuge the extracted specimen contained in the sample collection tube. Collect 80 µL of supernatant, dispense into the sample application window of a new test device and start afresh following the instructions mentioned above.

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Test Interpretation *(Fig. 3)*

Positive: Two lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T) *(Fig. 3a)*.

Note: The intensity of the colour in the test line region (T) will vary depending on the concentration of H. pylori antigen present in the specimen. Therefore, any shade of colour in the test line region (T) should be considered positive.

Negative: One coloured line appears in the control line region (C). No line appears in the test line region (T) *(Fig. 3b)*.

Invalid: Control line fails to appear *(Fig. 3c)*.
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 Preventis.

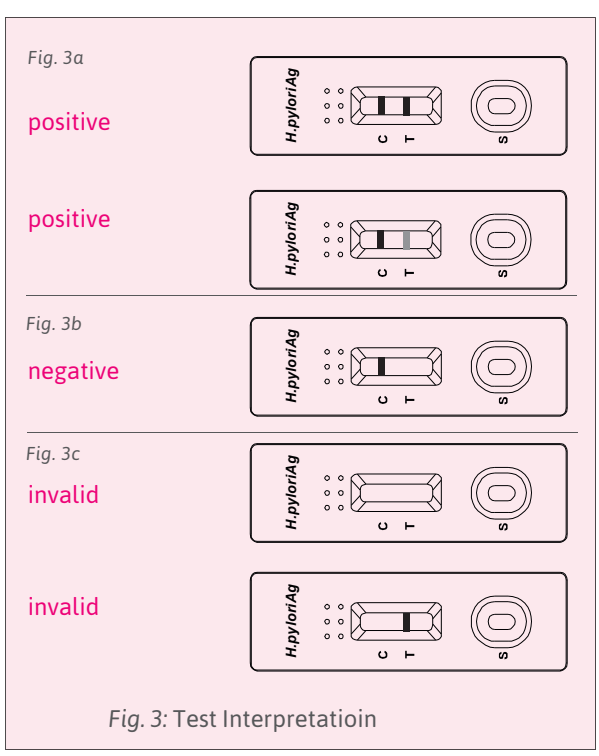

Fig. 3: Test Interpretatioin

Expected Values

The **PreventID® H. pylori Antigen** has been compared with Endoscope-based methods, demonstrating an overall accuracy of 98.6 %.

Test Characteristics

Sensitivity and Specificity

The **PreventID® H. pylori Antigen** has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. The result shows that the sensitivity of the **PreventID® H. pylori Antigen** is 98.8 % and the specificity is 98.4 % relative to Endoscope-based methods.

		Endoscope-based method		
		positive	negative	
PreventID® H. pylori Antigen	**positive**	168	3	171
	negative	2	189	191
		170	192	362

Relative Sensitivity: 98.8 % (95 % CI*:95.8 %–99.9 %)
Relative Specificity: 98.4 % (95 % CI*: 95.5 %–99.7 %)
Accuracy: 98.6 % (95 % CI*: 96.8 %–99.5 %)

*Confidence Interval

Between Day Reproducibility

Within-run precision has been determined by using 15 replicates of four specimens: negative, low titer positive, middle titer positive and high titer positive specimens. The specimens were correctly identified >99% of the time.

Between Lot Reproducibility

Between-run precision has been determined by 15 independent assays on the same four specimens: negative, low titer positive, middle titer positive and high titer positive specimens. Three different lots of the **PreventID® H. pylori Antigen** have been tested using these specimens. The specimens were correctly identified >99 % of the time.

Cross-reactivity

Cross reactivity with following organisms has been studied at 1.0E+09 organisms/ml. The following organisms were found negative when tested with the **PreventID® H. pylori Antigen:**

Acinetobacter calcoaceticus
Candida albicans
E.coli
Group A Streptococcus
Hemophilus influenza
Neisseria meningitides
Pseudomonas aeruginosa
Staphylococcus aureus
Acinetobacter spp
Chlamydia trachomatis
Enterococcus faecalis
Group B Streptococcus
Klebsiella pneumonia
Proteus mirabilis
Rotavirus
Adenovirus
Branhamella catarrhalis
Enterococcus faecium
Gardnerella vaginalis
Group C Streptococcus
Neisseria gonorrhea
Proteus vulgaris
Salmonella choleraesius

Interfering substances

The following potentially interfering Substances were added to *H. pylori* Antigen positive and negative specimens: Albumin 2000 mg/dL, Ascoribic acid: 20 mg/dL, Aspirin 20 mg/dL, Bilirubin 100 mg/dL, Caffeine: 40 mg/dL, Glucose 2000 mg/dL, Oxalic Acid: 60 mg/dL, Uric acid: 60 mg/dL, Urea 2000 mg/dL.
All tested substances had no effect on the test result.

Quality Control

Internal procedural controls are included in the test. A coloured line appearing in the control region (C) is an internal valid 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.

Test Limitations

1. The **PreventID® H. pylori Antigen** is for laboratory use only. The test should be used for the detection of *H. pylori* antigens in faeces specimens only. Neither the quantitative value nor the rate of increase in *H. pylori* antigens concentration can be determined by this qualitative test.
2. The **PreventID® H. pylori Antigen** will only indicate the presence of H. pylori in the specimen and should not be used as the sole criteria for *H. pylori* to be the etiological agent for peptic or duodenal ulcer.
3. As with all laboratory 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.
5. Following certain antibiotic treatments, the concentration of *H. pylori* antigens may decrease to the concentration below the minimum detection level of the test.

References

1. Marshall, BJ, McGechie, DB, Rogers, PAR and Glancy, RG. Pyloric Campylobacterinfection and gastroduodenal disease. Med. J. Australia. (1985), 149:439-44.
2. Soll, AH. Pathogenesis of peptic ulcer and implications for therapy. New England J. Med. (1990), 322: 909-16.
3. Hazell, SL, et al. Campylobacter pyloridis and gastritis I: Detection of urease as a markerof bacterial colonization and gastritis. Amer. J. Gastroenterology. (1987), 82(4): 292-96.
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 normalindividual with Helicobacter pylori infection. Am J Gastroenterol. 1996,91:1112-1115.

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Status: 2018-11-26

US: all products: Research Use Only. Not for use in diagnostic procedures.

Temperature limitation	Manufacturer
In vitro diagnostic device	Lot number
Catalogue number	Expiry date
To be used with	Do not reuse
Read user instructions	Contains sufficient for <n> tests

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