PreventID® **H. pylori**

Manual (FOR PROFESSIONAL USE)

REF KST18116GP

Intended use

The **PreventID® H. pylori** test is an immunochromatographic assay for the rapid, qualitative detection of antibodies (IgG and IgM) to *Helicobacter pylori* in whole blood, human plasma or serum. The **PreventID® H. pylori** test is intended as an aid in the diagnosis of *H. pylori* infections.

Introduction

Helicobacter pylori (H. pylori) is a spiral-shaped bacterium that can be found in the human stomach and duodenum. In order to be able to survive in the extremely acid environment of the stomach, *H. pylori* bacteria produce urease which in turn metabolises urea into bicarbonate and ammonia. Particularly, the highly corrosive ammonia affects the gastric mucosa adversely and might ause severe damage. Besides a possible gastritis, an *H. pylori* infection could eventually lead to a duodenal ulcer or a gastric tumour, resulting from the persisting immune response to the infection.

Traditional diagnosis of an *H. pylori* infection requires invasive measures such as gastroscopy and biopsy, which for most patients are rather burdensome. Alternatively, measuring *H. pylori* antibodies in serum provides information on a possible *H. pylori* infection.

Test Principle

The **PreventID® H. pylori** test is a sandwich immunoassay test. The test device contains an immobilised *Helicobacter pylori* antigen in the test reaction zone (T). A goat-anti-(rabbit IgG) antibody is immobilised in the control reaction zone (C). The sample moves from the specimen pad through the zone with *H. pylori* antigen-colloidal-gold and rabbit IgG-colloidal gold. Gold-conjugate-complexes are formed on the way to the reaction pad when the specimen contains antibodies against *H. pylori.* When the antibody – antigen – colloidal gold complexes are transported across the membrane and reach the respective immobilised *Helicobacter pylori* antigen on the membrane (T), they are trapped and will form a sandwich complex consisting of: immobilised antigen – antibody (analyte) – antigen – Colloidal Gold. Only when the applied blood sample contains a certain concentration of *Helicobacter pylori* antibodies, the formation of this sandwich complex will result in a visible purple colour line at (T). In case there are no *Helicobacter pylori* antibodies in the blood sample, the test region of the membrane will remain colourless (no test line visible). The liquid, together with the rabbit IgG coupled colloidal gold conjugate continues to move to the control line (C). There, this conjugate will form a complex with the immobilised anti IgG antibody on the membrane resulting in the formation of a purple coloured control (C) test line. This indicates that the test has been performed correctly.

Materials

Materials Provided

- Test devices (with sample droppers), individually packed TEST
- Bottle with buffer solution BUF
- Manual

Materials Required but not Provided: Timer, gloves, blood specimen collection tube (heparin, EDTA or sodium citrate) for venous blood; lancet (for finger tip blood); centrifuge for serum or plasma

Storage and Stability

Store the test between 4 °C and 30 °C; do not freeze. The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the testdevice from the pouch. Do not use it 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 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. Read the instruction carefully before performing the test.
7. If you have any questions please contact Preventis GmbH.

Specimen Collection

Whole blood:

Whole blood samples must be tested within 24 hours of drawing.

a) Capillary blood: Prick fingertip with a sterile lancet. Let flow **1 hanging drop** of blood into the sample application window.

b) Venous blood: Collect an anti-coagulated blood sample (sodium heparin or lithium heparin). Use the sample dropper to apply 1 drop heparin blood into the sample application window.

Plasma / Serum:

1. Centrifuge whole blood to get plasma/serum specimen.
2. If specimens are not immediately tested, they should be refrigerated at 2 – 8 °C . For a storage longer than 3 days keep in the freezer at -20 C. Specimens should be at room temperature before running a test. Use the sample within 24 hours.
3. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

Test Procedure

1. Remove the test device from the pouch and place it on a flat, dry surface.
2. Holding the sample dropper above the test device *(Fig. 1)* add **1 hanging drop of whole blood or serum/plasma** specimen into the sample application window. After the drop is absorbed into the sample application window, **add 2 drops of buffer solution** into the sample opening *(Fig. 2)*.
3. As the test begins to work, you will see a purple colour move across the result window in the center of the test device.
4. Interpret test results **within 5–10 minutes**. Do not read result after 10 minutes.

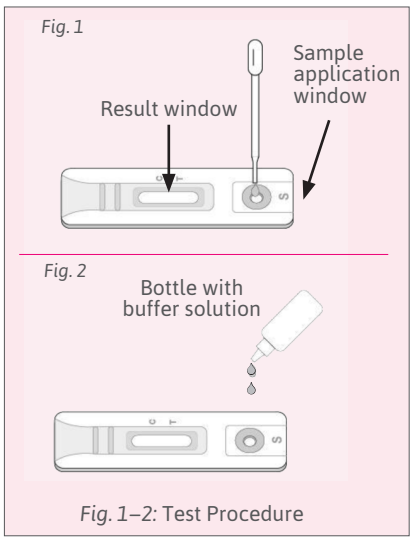

Fig. 1–2: Test Procedure

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Test Interpretation *(Fig. 3)*

1. As the test kit begins to work, a colour line will appear at the left section of the result window to show that the test is working properly. This line is the **control line (C)**.
2. The right section of the result window indicates the test results. If another colour line appears at the right section of the result window, this band is the **test line (T)**.

Note: Interpret the test within 5–10 minutes. The test should not be interpreted after 10 minutes!

Positive: The presence of two colour lines (C and T) within the result window – regardless of which line appears first – indicates a positive result *(Fig. 3a)*.
Note: Generally, the higher the analyte level in the specimen, the stronger the test line (T) colour will be. When the specimen analyte level is close to but still within the sensitivity limit of the test, the colour of the test line (T) will be very faint.

Negative: The presence of only one colour line within the result window indicates a negative result *(Fig. 3b)*.

Invalid: If no control line (C) is visible after performing the test, or if only the test line (T) appears, the test result is considered invalid *(Fig. 3c)*. Some causes of invalid results: not following the instructions correctly or the test is beyond the expiry date. It is recommended that the specimen be re-tested using a new test kit.

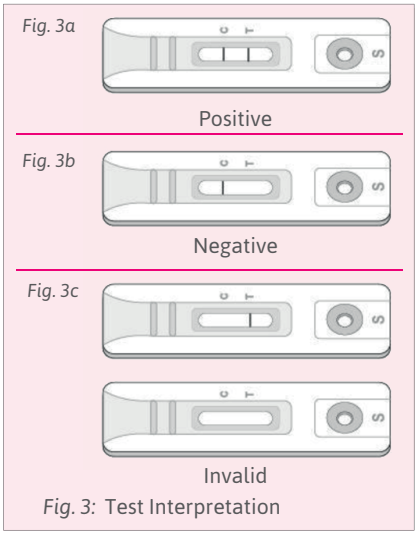

Fig. 3: Test Interpretation

Test characteristics

Clinical Sensitivity and Specificity

From patients who had clinical symptoms of gastrointestinal disease, biopsy samples as well as blood samples were obtained. The biopsy samples were tested by culture and histological methods. 150 patient samples were chosen which were classified to be positive for *H. pylori* according to biopsy and 160 patient samples were chosen which were classified to be negative for *H. pylori* according to biopsy.

The **sensitivity** of the **PreventID® H. pylori** test is 93 % (140/150) and the specificity is 93 % (150/160) when compared to the golden standard biopsy test method (confirmed by culture and histology).

Specificity study: The ability of the **PreventID® H. pylori** test to specifically detect *H. pylori* was challenged through cross reaction studies on serum samples containing known other closely related microorganisms such as Campylobacter fetus, Campylobacter jejuni and E. coli. Serum samples that are negative to the *H. pylori* test were spiked with various concentration levels of the above microorganisms. These samples were tested on the **PreventID® H. pylori** test. Each microorganism had 10 runs of the **PreventID® H. pylori** test. A total 30 test results indicated **PreventID® H. pylori**test does not cross-react with the above microorganisms.

Interference Study: Potentially interfering chemicals such as pain medication, lipids, hemoglobin, bilirubin and glucose were supplemented to negative normal serum specimens. Above baseline specimens as well as *H. pylori* positive specimens were then analyzed. All interference studies indicated none of the above substances interfered with the **PreventID® H. pylori** test procedure. Baseline serum samples with supplementation of potentially interfering substances gave consistently negative test results. The serum sample positive to *H. pylori* scored consistently positive.

Test Limitations

The content of this kit is for the use in the qualitative detection of *H. pylori*-specific antibodies and does not indicate the titer of the antibody in the sample. The test should be used only to evaluate patients with clinical signs and symptoms suggestive of gastrointestinal disease. Test results are only reliable if you follow the instructions for use carefully. Use the test only once. Although the test is very accurate in detecting antibodies to *H. pylori*, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained.
As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

References
1. Warren JR and B Marshall: Unidentified curved bacillus on gastric epithelium in active chronic gastritis. Lancet 1983;1-137
2. Peterson WL: Helicobacter pylori and peptic ulcer disease. N Engl J Med 1991; 324:1043-1047
3. Mcguigan JE: Peptic ulcer and gastritis. In: Harrison's Principles of Internal Medicine, 12th Edition, 1988, Chapter 238,1229-1248
4. Podolsky I et al.: Prevalence of C. pylori in healthy subjects and patients with peptic diseases. Gastroenterology 1989: Suppl: A394. Abstract
5. Talley NJ et al.: Serodiagnosis of Helicobacter pylori: comparison of enzyme-linked immunosorbent assays. J.Clin Microbiol 1991;29:1635-1639

Short instruction PreventID® H. pylori

1. Collect the sample from whole blood, plasma or serum.
2. Let **1 hanging drop of sample** flow into the sample application window.
3. Add **2 drops of buffer solution** into the sample opening.
4. Interpret the test result at **5–10 minutes**.

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Status: 2018-11-29

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
Keep away from sunlight	Do not reuse
Read user instructions	Contains sufficient for <n> tests

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