



Biocard *Helico pylori* Ag

One Step *H. pylori* Antigen Test Device

A rapid, one step test for the qualitative detection of *Helicobacter pylori* (*H. pylori*) antigens in human faeces.

For professional *in vitro* diagnostic use only.

INTENDED USE

The *H. pylori* Device test 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.

SYNTHESIS

Helicobacter pylori (*H. pylori*) is a small, spiral-shaped bacterium that is found in the surface of the stomach (epithelial lining) and duodenum (mucous layer). *H. pylori* causes duodenal ulcers and gastric ulcers.

The importance of *Helicobacter pylori* testing has increased greatly since the strong correlation between the presence of bacteria and confirmed gastrointestinal diseases (stomach and duodenum) like gastritis, peptic ulcer disease and gastric carcinoma. Invasive and non-invasive methods are used to diagnosis *H. pylori* infection in patients with symptoms of gastrointestinal disease.

PRINCIPLE

The Biocard *Helicobacter pylori* Ag device is a qualitative lateral flow immunoassay for the detection of *Helicobacter pylori* antigen in human faeces samples. The membrane is pre-coated with monoclonal antibodies against *H. pylori* antigens on the test line region. During testing, the sample reacts with the particle coated with anti-*H. pylori* antibodies which was pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane will react with the mixture conjugate and generate a coloured line. A red coloured band always appears in the control line and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- Do not use the test if pouch is damaged.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test should be discarded in a proper biohazard container after testing.
- The test must be carried out within 2 hours of opening the sealed bag.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze.

Cat. no. 4-002-010

- 10 Disposable test sticks
- 10 Test tubes
- 10 Sterile sampling swabs
- 0,5 ml Positive Control
- 5 ml Biocard *H. pylori* Buffer
- Instructions for use

SPECIMEN COLLECTION AND PREPARATION

Collect sufficient quantity of faeces (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-4°C) for 1-2 days prior to testing. For longer storage the specimen must be kept frozen at -20°C. In this case, the sample will be totally thawed, and brought to room temperature before testing.

PROCEDURES

Place a test tube in a workstation. Add 6 - 8 drops of Biocard™ Rota Buffer (approximately 225 µl) into the test tube.

Code: *H. pylori* Device-F Apr 08
Revision: April 2008



Faecal specimens are collected using a cotton swab. The swab with a small amount of sample (approximately 25 µg) is put in the test tube. Please take care that not too much sample is caught on the inside of tube. The dilution should be appr. 1:10. The faecal sample is suspended in the buffer by rotating the swab.

Remove the swab from the tube. The test tube should stand at room temperature for 3 minutes to allow coarse particles to sediment. Samples can be stored for seven days refrigerated before the testing procedure.

Allow the tests, stool samples and buffer to reach to room temperature (15-30°C) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the *Helicobacter pylori* Ag device from its sealed pouch and use it as soon as possible.
3. Use a separate device for each sample. With the provided dropper, dispense exactly 4 drops into the specimen well (S). Start the timer.
- 4.- Read the result at **10 minutes** after dispensing the sample.

INTERPRETATION OF RESULTS

Illustration 3



POSITIVE: Two red lines appears across the central window, in the result line region (test line marked with the letter T) and in the control line region (control line marked with the letter C).

NEGATIVE: Only one band appears across the control line region marked with the letter C (control line).

INVALID: A total absence of the control coloured band regardless the appearance or not of the test line. Note: Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents 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 and contact you local distributor.

NOTES ON THE INTERPRETATION OF RESULTS

The intensity of the red coloured band in the result line region (T) will vary depending on the concentration of antigens in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

QUALITY CONTROL

Internal procedural controls are included in the test:

- A line appearing in the control line region (C). It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS

1. *H. pylori* Ag device will only indicate the presence of *H. pylori* in the specimen (qualitative detection) and 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 test.
2. An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.

3. Some stool samples can decrease the intensity of the control line.
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. This test provides a presumptive diagnosis of *Helicobacter pylori* infections. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

EXPECTED VALUES

Studies have found that more than 90% of patients with duodenal ulcer and 80% of patients with gastric ulcer are infected with *H. pylori*. The *H. pylori* Device has been compared with different methods: cultures, Urea Breath Test and Urease Test, demonstrating an overall accuracy of >92%.

PERFORMANCE CHARACTERISTICS

Sensitivity, Specificity and Cross Reactivity

It was performed an evaluation using Biocard *Helicobacter pylori* Ag device with specimens obtained from patients with the same as *H. pylori* infection symptoms and from asymptomatic individuals. The *Helicobacter pylori* Ag device was evaluated compared with a commercial EIA Test (Premier Platinum HpSA EIA test).

Results of sensitivity: >99% compared with Premier Platinum HpSA EIA test.

The *H. pylori* Device was evaluated compared with another commercial EIA Test (Amplified IDEIATM Hp STAR™).

Results of specificity >99% compared with Amplified IDEIATM Hp STAR™.

Cross-Reactivity

It was performed an evaluation to determine the cross reactivity of *H. pylori* Device. There is not cross reactivity with common intestinal pathogens, other organisms and substances occasionally present in feces.

- Rotavirus
- Adenovirus
- *Escherichia coli*
- *Campylobacter*
- *Giardia lamblia*
- Human Hemoglobin
- Ig G bovine (immunoglobulins)
- HCG hormone (Human Chorionic Gonadotropin)

REFERENCES

- 1- Cutler AF. Testing for *Helicobacter pylori* in clinical practice. *Am j. Med.* 1996; 100:355-415
- 2- Soll, AH. Pathogenesis of peptic ulcer and implications for therapy. *New England J. Med.* (1990), 322: 909-16.
- 3- Martin J. Blaser. *Helicobacter pylori and gastric diseases.* *BMJ*; 316: 1507-1510 (1998).

SYMBOLS FOR IVD COMPONENTS AND REAGENTS



Manufacturer

Authorized representative



Contains sufficient for <n> tests



Catalogue Code



Lot Number



For *in vitro* diagnostic use only



Consult instructions for use



Keep dry



Temperature limitation



Use by



Manufacturer
Ani Biotech Oy
Finland
info@anibiotech.fi