CoproStrip™ H.pylori

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

Instruction Manual
REF: 41221

Test kit for 20 determinations
For professional *in vitro* diagnostic use only.
Store at 2-30°C. **Do Not Freeze**

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Intended Use

The *CoproStrip™ H.pylori* test is a rapid chromatographic immunoassay for the qualitative detection of *H. pylori* antigens in human feces specimens to aid in the diagnosis of *H. pylori* infection.

Summary and Explanation of the Test

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 *CoproStrip™ H.pylori* is a qualitative lateral flow immunoassay for the detection of *Helicobacter pylori* antigen in human feces samples. The membrane is pre-coated with monoclonal and polyclonal 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 green 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.

Reagents and Materials Supplied

- Devices
- Instruction for use (upon request)
- Specimen collection vial with buffer

Materials Required but not Supplied

- Specimen collection container
- Disposable gloves
- Timer

Storage and Stability

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC/36-86ºF). 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.

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.
- The presence of yellowish lines in the results window (control and test line zone) that are visible **before using the test** are normal. That does not mean failure of the test's functionality.

Specimen Collection and Preparation

Collect sufficient quantity of feces (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 (2-8°C/36-46.4ºF) for 1-2 days prior to testing. For longer storage (maximum 1 year) the specimen must be kept frozen at -20°C/-4ºF. The sample should be totally thawed and brought to room temperature before testing.

Test Procedure

To process the collected stool samples (see illustration 1):
Use a separate specimen collection vial for each sample. Unscrew the cap of the vial and introduce the collector spiral

stick 4 times into the faecal specimen to pick approx. 50 mg of sample. Note, not to exceed the stick's spiral part to avoid extra faecal material. Close the vial with the buffer and stool sample. Vortex the vial in order to assure good sample dispersion. For liquid stool samples, aspirate the faecal specimen with a dropper and add 125µL into the specimen collection vial with buffer.

Test Procedure (see illustration 2)
Allow the tests, stool samples and buffer to reach to room temperature (15-30ºC/59-86ºF) prior to testing. Do not open pouches until ready to perform the assay.
1. Remove the *CoproStrip™ H. pylori* from its sealed pouch and use it as soon as possible.
2. Shake the specimen collection vial to assure a good sample dispersion. Break off the tip of the vial.
3. Use a separate device for each sample. Dispense exactly 3 drops into the specimen well (S). Start the timer.
4. Read the result at **10 minutes** after dispensing the sample.

Illustration 1

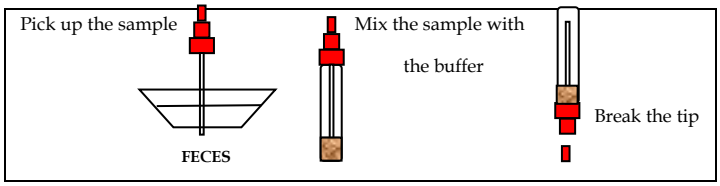
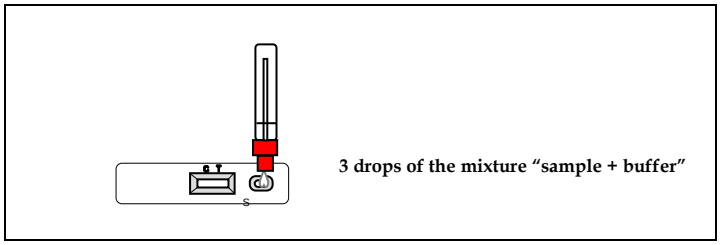
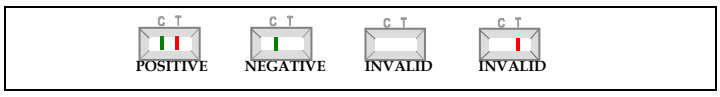


Illustration 2



Interpretation of Results

Illustration 3



POSITIVE: Two lines appear across the central window, a **red** test line marked with the letter T, and a **green** control line marked with the letter C.

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

INVALID: Total absence of the green control coloured line regardless of the appearance or not of the red test line. 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 your local distributor. See illustration 3.

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.

Limitation of Procedure

- *CoproStrip™ H. pylori* 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 feces specimens only. Neither the quantitative value nor the rate of increase in *H. pylori* antigens concentration can be determined by this test.
- An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
- Some stool samples can decrease the intensity of the control line.
- 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.
- 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.
- Bloody stool samples can contain components that may cause non-specific reactions in the test. Every bloody stool sample whose result is positive should be followed up with other techniques of diagnosis to confirm the result.
- Mucous stool samples may cause non-specific reactions in the test- Every mucous stool sample whose result is positive should be followed up with other techniques of diagnosis to confirm the result.

Quality Control

Internal procedural controls are included in the test:
- A green line appearing in the control line region (C) confirms sufficient specimen volume and correct procedural technique.

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 *CoproStrip™ H.pylori* has been compared with different methods: cultures, Urea Breath Test and Urease Test, demonstrating an overall accuracy of >92%.

Performance Characteristics

DETECTION LIMIT

The detection limit test is 0.09 - 0.78ng/mL of recombinant outer membrane protein.

SENSITIVITY AND SPECIFICITY

An evaluation was performed using *CoproStrip™ H.Pylori* with specimens obtained from patients with *H. pylori* infection symptoms. The *CoproStrip™ H.pylori* was evaluated and compared with a commercial ELISA assay (Amplified IDEIA™ Hp StAR™). The results had obtained a Sensitivity: >94% and specificity >99%.

In a second study evaluating the performance of the *CoproStrip™ H.pylori*. vs. a commercial qPCR kit for *Helicobacter pylori*, 116 specimens were obtained from symptomatic patients for *H. pylori* infection. The results had shown high accordance between the two methods.

	H. pylori Real-Time PCR (CE Mark)			
CoproStrip™ H.pylori		POS	POS	Total
	POS	54	1	55
	NEG	1	60	61
	Total	55	61	116

Sensitivity 98.2%;

Specificity 98.4%

PPV 98.2%; NPV 98.4%

CROSS-REACTIVITY

An evaluation was performed to determine the cross reactivity of *CoproStrip™ H.pylori*. There is no cross reactivity with common intestinal pathogens, other organisms and substances occasionally present in feces.

- *Campylobacter*
- *Clostridium difficile*
- *Listeria monocytogenes*
- *Salmonella*
- *Yersinia enterocolitica*
- *Shigella*
- *Staphylococcus aureus*
- *Escherichia coli O157:H7*

References

1. Cutler AF. Testing for *Helicobacter pylori* in clinical practice. *Am j. Med.* 1996; 100:35S-41S
2. Soll, AH. Pathogenesis of pectic ulcer and implications for theraphy. New England J. Med. (1990), 322: 909-16.
3. Martin J. Blaser. *Helicobacter pylori and gastric diseases*. BMJ; **316**: 1507-1510 (1998).

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Symbols for IVD components and Reagents			
	Manufacturer	IVD	For *in vitro* diagnostic use only
EC REP	Authorized representative		Consult instructions for use
Σ n	Contains sufficient for <n> tests		Keep dry
REF	Catalogue Code		Temperature limitation
LOT	Lot Number		Use by
DIL	Sample diluent		