



For information Use only- Not to be used for performing the assay. Refer to the insert accompanying the kit

Pylori-Strip

In vitro Rapid Diagnostic Test for the detection of *Helicobacter pylori* in faecal specimens

FOR IN VITRO USE

For professional use only

Reference : C-1019, 25 tests per kit

C-1519, 10 individually packaged tests per kit, sampling instruments supplied

C- 1219, 20 individually packaged tests per kit

EN

I. INTRODUCTION.

Helicobacter pylori is a helical-shaped gram-negative bacteria that lives in the mucous layer of the stomach and duodenum, causing peptic ulcer disease and chronic gastritis; it is also strongly associated with gastric malignancies and has been classified as a class I carcinogen.¹

It is transmitted mainly through feco-oral route in developing countries and gastro-oral route in developed countries. Both ways by which a person becomes colonized and by which a colonized patient becomes infected are still under investigation. *H. pylori* infection can be diagnosed by non-invasive techniques (serological assay, the ¹³C-urea breath test (UBT) and the stool antigen test) or by invasive techniques (endoscopy with biopsies for histology, culture and a rapid urease test). Although detection by endoscopy is highly specific, cost is high and this procedure is highly uncomfortable for the patient.

The European *Helicobacter pylori* Study Group has defined the Guidelines for the Management of *Helicobacter pylori* infection (the Maastricht III Consensus Report).²

The test-and-treat strategy is the strategy of choice in all patients with functional dyspepsia in high-prevalence (>20%) population and is an appropriate option for patients with non-investigated dyspepsia or in low prevalence populations. Recommended non-invasive tests are UBT and the stool antigen tests. Proton pump inhibitors (PPI) are a source of false negative diagnostic tests except serology, so PPI should be stopped for at least 2 weeks before to perform diagnostic test. It is recommended to follow up patients after *H. pylori* eradication with UBT or a stool antigen test.

H. pylori is found in more than 90% of people with a duodenal ulcer and in approximately 80% of those who have a gastric ulcer. The infection with *H. pylori* is one of the most chronic infections throughout the world: 20 to 90% of adults are infected by country; the infection is more common in developing countries than in industrialized ones. The high incidence of this infection in the population and the consequences it entails, including the risk of developing stomach cancer, justify the provision of a rapid diagnostic tool against this bacterium

The *H. pylori* Strip-Test is a highly sensitive and specific rapid membrane assay that uses monoclonal antibody to detect the presence of *H. pylori* antigens in stool specimens.

II. PRINCIPLE OF THE TEST

This is a ready-to-use test that is based on the homogeneous membrane system technology with latex microspheres. The faecal sample must be diluted in the HC dilution buffer that is supplied with the test. A nitrocellulose membrane is sensitized with antibodies directed against *Helicobacter pylori*. The test's specificity comes from a monoclonal antibody directed against an antigen of *Helicobacter pylori*, that is conjugated to latex microspheres. This conjugate is dried on a polyester membrane.

When the strip is dipped into the liquid phase of the faecal suspension, the solubilised conjugate migrates with the sample by passive diffusion and the conjugate and sample material come into contact with a monoclonal antibody directed against a specific antigen of *Helicobacter pylori*. If the sample contains this specific *Helicobacter pylori* antigen, the complex formed of-*Helicobacter pylori* antigen and conjugate remains bound to the monoclonal antibody adsorbed to the nitrocellulose and a red line develops. The result is visible within ten minutes. The solution continues to migrate to encounter a second reagent (control reagent) that binds the control conjugate, thereby producing the green control line that confirms that the test is working properly.

III. REAGENTS AND MATERIALS

Each kit contains: Pylori-Strips, a HC dilution buffer and optional components (for C-1519):

I. Pylori- Strip

Each Pylori-Strip is sensitized with a mouse monoclonal antibody directed against a specific antigen of *Helicobacter pylori* and with a goat anti-chicken IgY reagent.

The anti-*Helicobacter pylori* conjugate is produced with a mouse monoclonal antibody that recognizes the same specific antigen of *Helicobacter Pylori*. The control conjugate is produced with chicken IgY.

These strips come in a container or a pouch with a desiccant.

2. HC Dilution buffer (15 ml)

Saline solution buffered to pH 7.5 with Tris and containing EDTA, NaN₃ (<0.1%), a detergent, and charged proteins.

3. Instruction for use (1 X)

4. Required materials not supplied (supplied with C-1519)

- 3 or 5 ml test tubes;
- inoculating loops for taking the faecal samples.

IV. SPECIAL PRECAUTIONS

- All operations related to the use of the test must be performed in accordance with Good Laboratory Practices.
- The Pylori-Strips are for *in vitro* diagnostic use only.
- Avoid touching the nitrocellulose with your fingers.
- Wear gloves when handling the samples.
- Dispose of gloves, swabs, test tubes, and sensitized strips in accordance with GLP.
- Never use reagents from another kit.
- In case of the strips coming in a tube, the tube must be recapped as soon as the necessary number of strips has been removed, since the strips are sensitive to humidity. Make sure that the desiccant sachet is present.
- If strips are stored in individual pouches, pouch must be opened with care to avoid damaging the strip.
- Two green lines indicate the antibody immobilisation sites. They disappear during the course of the test.
- Discard the buffer solution if it is contaminated with bacteria or mould.
- The reagents' quality cannot be guaranteed beyond their shelf-life dates or if the reagents are stored under inappropriate conditions.

To avoid diluting the conjugate in the solution, take care not to immerse the strip above the line placed under the arrow.

V. STORAGE

An unopened Pylori-Strip kit may be kept between 4 and 30°C and used until the shelf-life date on the packaging. The strips remain stable for 15 weeks (in the closed container) after the bottle is opened if they are kept at between 4 and 30°C and in a dry environment. Real-time long-term stability is under evaluation. Intermediate results are available at Coris BioConcept. The Pylori- strips and the buffer must not be frozen.

VI. SAMPLES

The stool specimens must be tested as soon as possible after they are collected. If necessary, they may be stored at 2-8°C for 24 hours or -20°C for longer periods of time. Make sure that the specimens are not treated with solutions containing formaldehyde or its derivatives.

VII. PROCEDURE

Preparations:

If the Pylori-Strip kit was kept at 4°C, let all the reagents in the unopened packaging warm up to room temperature before proceeding with the test. Write the patient's name or specimen number on the test tube (prepare one test tube per sample). Place the labelled test tubes in a rack.

Procedure:

1. Add 0.5 ml or 15 drops of the dilution buffer solution to each tube.
2. Dip the inoculating loop containing the stool sample into the tube. **The dilution ratio must be at most 4% w/v. For liquid samples, take 2 loops of 10 µL and for solid samples, take 1 loop.**
3. Stir to homogenize the solution and let to stand for 1-2 minutes.
4. Discard the inoculating loop and dip the sensitized strip in the direction indicated by the red arrow.
5. Let react for 10 minutes
6. **Result must be read on still wet strip**

VIII. INTERPRETING THE RESULTS

The results are to be interpreted as follows:

One green line = negative
One green line AND one red line = positive
No line = invalid*

*The absence of the control line, which is the upper green line, makes the result invalid. In this case, the sample must be retested.

The intensity of the test line may vary according to the quantity of antigens found in the sample. Any signal, even weak, on each test line must be regarded as a positive result. Nevertheless, the test is qualitative and cannot predict the quantity of antigens present in the sample. The clinical presentation and other test results must be taken into consideration to establish diagnosis. During the drying process, a very faint shadow may appear at the test line. It should not be regarded as a positive result.

To store the results, let the strip dry after removing the absorbent material at its base.

IX. QUALITY CONTROL

In accordance with Good Laboratory Practices, we recommend checking the test's performance regularly in line with the laboratory's requirements.

X. PERFORMANCES

A. Sensitivity - Specificity (Correlation):

1°) The kit was validated on 153 faecal samples by comparison with an EIA and with an ICT method by a third party (Germany)

Pylori-Strip	EIA	Positive	Negative	Total
Positive		57	1	58
Negative		2	33	35
Total		59	34	93

Sensitivity: 96.6 % Positive Predictive Value: 98.3 %
 Specificity: 97.1 % Negative Predictive Value: 94.3 %

Pylori-Strip	ICT competitor	Positive	Negative	Total
Positive		24	0	24
Negative		2	34	36
Total		26	34	60

Sensitivity: 92.3 % Positive Predictive Value: 100 %
 Specificity: 100 % Negative Predictive Value: 94.4 %

2°) The test-Pylori Strip was also evaluated on a panel of 18 clinical strains. Each of these strains showed a different profile of sensitivity to antibiotics. They are representative of circulating strains, some of which have resistance. The test-Pylori Strip detect all these clinical isolates. .

B. Accuracy:

To check the intra-lot accuracy, one *Helicobacter pylori* positive sample and a HC dilution buffer solution (as negative control sample) have been tested 15 times on sticks of the same production lot in the same experimental conditions. All observed results were similar as expected.

To check the inter-lot accuracy, same samples (positive in *Helicobacter pylori*, and HC dilution buffer) were tested on three different production lots. All results were similar as expected.

C. Interference

Cross-reactivity to samples positive for the following pathogens was tested and found to be negative: Rotavirus, Coronavirus, 40/41 Adenovirus, *Nocardia asteroides*, *Streptococcus pneumoniae*, HSV, Rhinovirus, Enterovirus, *Moraxella catarrhalis*, *Streptococcus pyogenes*, *Giardia lamblia*, *Candida albicans*, *Aspergillus niger*, *Haemophila influenza*, *Staphylococcus aureus*, *Campylobacter jejuni*, *Legionella pneumophila*, *Cryptosporidium parvum*, *E.coli* F5, *E. coli* CS31, *E.coli* strains (ATCC25922, ATCC35150).

XI. LIMITS OF THE KIT

Pylori-Strip kit results must be compared with all other available clinical and laboratory information.

A positive test does not rule out the possibility that other pathogens may be present.

The Pylori-Strip kit is an acute-phase screening test. Stool specimens that are collected after this phase may contain antigen titers below the reagent's sensitivity threshold.

XII. TECHNICAL PROBLEMS / COMPLAINTS

If you encounter a technical problem, or if performances do not correspond to those indicated in this package insert:

- 1- Note the lot No. of the kit in question
- 2- If necessary, store the problem sample in the freezer as soon as possible

3- Contact Coris Bioconcept or your local distributor.

XIII. BIBLIOGRAPHIC REFERENCES

1. Ricci, C., Holton, J. & Vaira, D. Diagnosis of *Helicobacter pylori*: invasive and non-invasive tests. *Best Pract Res Clin Gastroenterol* **21**, 299-313 (2007).
2. Malfertheiner, P. et al. Current concepts in the management of *Helicobacter pylori* infection: the Maastricht III Consensus Report. *Gut* **56**, 772-81 (2007).

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