



# H. pylori Antigen Rapid Test

Rapid qualitative immunochromatographic detection of  
Helicobacter pylori antigen in human stool



## ORDER INFORMATION

REF	Kit size
GD6561 00	30 tests
GD6562 00	15 tests

## INDICATION

Helicobacter pylori (Hp, called too Campylobacter pylori) is a bacterium with a spiral morphology, flagellated, gram negative, that infects the gastric mucosa and causes various gastrointestinal diseases like the non ulcerous dyspepsia, gastric and duodenal ulcers, active gastritis and can increase the risk of stomach adenocarcinoma, so that Hp was classified like the carcinogen agent kind I.

There are different families of Hp isolated: between these, the kind that express the CagA antigen is strongly immunogenic, so clinically important because associated at the cytotoxic factor. From literature's data it is determined that in infected subjects that have the antibodies against the CagA gene product, the risk of gastric not cardiac cancer is five times greater than the group of infected subjects from a bacterial family CagA negative.

The presence of the antigen itself support the persistence of the infection, the ulceration and besides the protein associated at the antigen, vacuolizant-toxin VacA, is frequently cause of strong polymorphonucleate infiltrations in the gastric mucosa.

This antigen associated at others like CagII, CagC, besides seems start an immediate inflammatory response that can support ulcerations (peptic ulcer), dietary allergy, and a reduction of the therapy effects.

For the diagnosis of infections caused from this bacterium are currently at disposal different kind of invasive and non-invasive methods. The invasive methods request the execution of the stomach mucosa's endoscopy, with the following histological, cultural test and the ureasi's test; these kind of techniques have high costs and high execution times. In alternative, the non-invasive methods are at disposal, like the breath test, but it is difficult to execute and not much selective in the result; or the classic methods in ELISA and in Immunoblotting.

## PRINCIPLE

The test is based on a chromatographic non invasive test strip, simple to use, rapid and most accurate in the result. The membrane is pre-coated with monoclonal antibodies, on the test band region, against Hp antigens. During testing, the sample is allowed to react with the coloured conjugate (anti-Hp monoclonal antibodies-red polystyrene microspheres) which was pre-dried on the test strip. The mixture then moves upward on the membrane by capillary action. As the sample flows through the test membrane, the coloured particles migrate. In the case of a positive result the specific antibodies present on the membrane will capture the coloured conjugate (region T). The mixture continues to move across the membrane to the immobilized antibody placed in the control band region (C), a band, similar to the test band, always appears. To serve as a procedural control and as an internal control for the reagents, a coloured band at the control region (C) will always appear regardless of the presence of Hp antigen.

## COMPOSITION

**H. pylori Antigen Rapid Test devices**, sealed in pouch.

Ref. GD6561 00	n° 30
Ref. GD6562 00	n° 15

**Stool collection tubes** containing sample diluent.

Ready to use.

Ref. GD6561 00	n° 30
Ref. GD6562 00	n° 15

**Labels** for sample identification (ID) of the sample collection tubes.

Ref. GD6561 00	n° 30
Ref. GD6562 00	n° 15

## Storage and stability

The kit can be stored at 4 - 30 °C. The test device must remain in the sealed pouch until use. **Do not freeze.**

The test kit should be kept away from direct sunlight, moisture and heat.

Stable up to expiry date printed on the sealed pouch.

Do not use test kit beyond expiry date.

## SPECIMEN

Feces.

If the test can not be executed in a short time, the sample can be stored for 24-48 hours at 2-4 °C. For longer storage the samples can be frozen at -20 °C.

## Specimen collection and preparation

Use the stick (Fig 1) to pick up a little sample. Close the tube with the diluent and stool sample. Shake the tube in order to assure good sample dispersion.

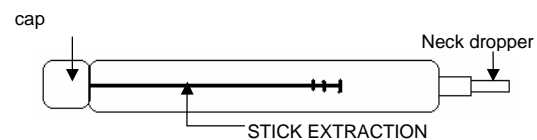


Fig. 1

## PROCEDURE

Allow reagents and samples to reach working temperature (15-30 °C) before using.

Use a separate stool collection tube and device for each sample or Control. Do not open pouches until ready to perform the assay.

1. Shake properly the container to dissolve the sample.
2. Break the superior end of the extraction bottle cap and put 5 drops or 150 µl into the sample well (S) of the cassette. Generally the reactivity will appear in 2-3 minutes.
3. Read the result **within 10 minutes**.

## INTERPRETATION OF RESULT

**Negative:** Only one green band appears in the Control area (C). This means that the sample does not contain Hp antigen and the test is correct.

**Positive:** One red band appears in the Test area (T) and a green one in the Control area (C). This means that the sample contains the Hp antigen.

**Invalid:** A total absence of the control coloured band regardless the appearance or not of the result line. Review the procedure, check reagent stability or deterioration and repeat the test with a new device. If the problem persists, discontinue using the test kit and contact your local distributor.

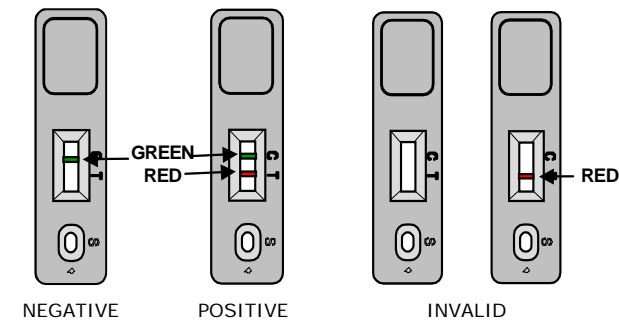


Fig. 2

**Note:**

- 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.
- The antibodies used to elaborate the Hp Ag recognise epitopes present in the antigen found in stool of patients, as well as in preparations from the bacteria cultures in vitro. Sonicated *Helicobacter pylori* extract from different commercial samples reacts with Hp antigen.

**QUALITY CONTROL**

Internal procedural controls are included in the test. A GREEN line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be clear and not interfere with the ability to read the result.

**ANALYTICAL PERFORMANCES****Sensitivity**

A culture of Hp bacteria was sonicated, centrifuged and its protein concentration was determined. This reference antigen preparation was diluted in the PBS-BSA buffer and tested in accordance with the kit instructions. The detection limit of Hp is 4-8 ng/ml.

**Specificity**

The evaluation was conducted comparing the results obtained using the H. pylori Antigen Rapid Test to another available commercial ELISA assay.

The detection of *Helicobacter pylori* showed 95% of concordance with the commercial ELISA assay.

The possibility for interference by human anti-mouse antibodies (HAMA) or high levels of RF in the stools sample, has not been evaluated.

Some stool samples could produce control lines with a light red colour.

**LIMITATIONS**

1. The test must be carried out within 2 hours of opening the sealed bag.
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 green line.
4. This test provides a presumptive diagnosis of *Helicobacter pylori* infections. A confirmed infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated must be based in the correlation of the results with further clinical observations.

**PRECAUTIONS IN USE**

The reagents contain inactive components such as preservatives (Sodium Azide or others), surfactants etc. The total concentration of these components is lower than the limits reported by 67/548/EEC and 88/379/EEC directives about classification, packaging and labelling of dangerous substances. However, the reagents should be handled with caution, avoiding swallowing and contact with skin, eyes and mucous membranes.

The use of laboratory reagents according to good laboratory practice is recommended.

**Waste management**

Please refer to local legal requirements.

**REFERENCES**

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5. EU-Dir 1999/11 Commission Directive of 8 March 1999 adapting to technical progress the principles of good laboratory practice as specified in Council Directive 87/18/EEC.