

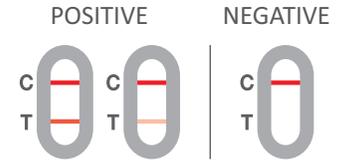


Gastrointestinal



berkeleyhealth HELICOBACTER PYLORI ANTIGEN

Self-test for the detection of the *Helicobacter pylori* antigen in the faeces



HELICOBACTER PYLORI

Helicobacter pylori is a bacterium that chronically infects more than half of the world's population and plays a causative role in the pathogenesis of chronic gastritis, peptic ulcer diseases, gastric cancer and mucosa-associated lymphoid tissue lymphoma. The considerable burden of these *H. pylori*-related outcomes means that there is an acute demand for accurate diagnosis of this infection. Several detection methods have already been developed, such as culture, histological staining, the urea breath test (UBT) but a simple, non-invasive, inexpensive and accurate diagnostic test remains the goal. One of the simplest way to detect infection is by checking the presence of specific antigens for the bacterium that are excreted through the faeces. HELICOBACTER PYLORI ANTIGEN TEST can detect the presence of these antigens in few minutes.

WHO ARE THE INTENDED USERS

Everyone who has gastric symptoms, ulcers can sometimes bleed, causing anemia over long periods of time.

WHY - BENEFITS

In 1994, the National Institutes of Health recognized that most recurrent duodenal and gastric ulcers were caused by *H. pylori* and antibiotic treatment was recommended. In the same year, the International Agency for Research on Cancer (IARC) declared *H. pylori* to be a group I human carcinogen for gastric adenocarcinoma.

TEST PRINCIPLE

HELICOBACTER PYLORI ANTIGEN TEST is an immunochromatographic test that detects the presence of specific *Helicobacter pylori* antigens in stools by using special monoclonal antibodies conjugated with gold and integrated into the reactive strip.

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
10 ng/mL	95.2%	96.6%	96%

Performance data obtained by clinical study with 100 participants enrolled. ImmunoCard STAT!® HpSA® has been utilized as reference method.

CONTENT:

1 sealed aluminium pouch containing: 1 test device and 1 desiccant bag; 1 vial with collection stick and dripper, containing the diluent; 1 small sheet for the collection of the sample; 1 instructions for use leaflet.

CLINICAL EVIDENCES

- Shimoyama T. "Stool antigen tests for the management of *Helicobacter pylori* infection." *World Journal of Gastroenterology*. 2013;19(45):8188-91.
- Ana Isabel Lopes, Filipa F Vale, Mónica Oleastro. "Helicobacter pylori infection - recent developments in diagnosis." *World Journal of Gastroenterology*. 2014 July 28; 20(28):9299-9313.
- Andreas Mentis, Philippe Lehours, and Francis Francis Megraud. "Epidemiology and Diagnosis of *Helicobacter pylori* infection". *Helicobacter*. 2015 Sep;20 Suppl 1:1-7.
- Zagari RM, Rabitti S, Eusebi LH, Bazzoli F. "Treatment of *Helicobacter pylori* infection: A clinical practice update." *Eur J Clin Invest*. 2018 Jan;48(1). doi: 10.1111/eci.12857

HOW TO USE IT

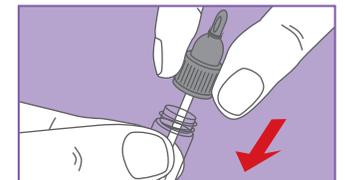
1) Attach the two adhesive surfaces of the stool-collecting sheet on the toilet seat surface.



2) Dip the stick into the faeces in three different points of the sample.



3) Screw on the cap, immersing the stick in the stool extraction liquid, and shake the vial.



4) Break the end of the cap, freeing the dropper portion. Dispense 3 drops of the diluted stool sample in the well shown on the cassette.

