



HELICOBACTER PYLORI ANTIGEN RAPID TEST

Rapid immunochromatographic test for the qualitative detection of *Helicobacter pylori* Antigen in stool samples



HELICOBACTER PYLORI

Helicobacter pylori is a bacterium whose ideal habitat is the human gastric mucosa. The infection is estimated to affect 2/3 of the world's population and it is often asymptomatic, but it can sometimes cause gastritis and ulcers in the stomach or in the duodenum segment of the small intestine. Ulcers can sometimes bleed, causing anemia over long periods of time. In the long term, infected people are 3 to 6 times more likely to develop stomach cancer.

WHO ARE THE INTENDED USERS

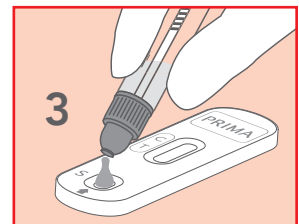
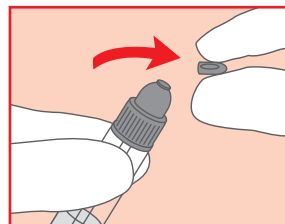
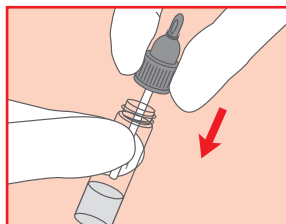
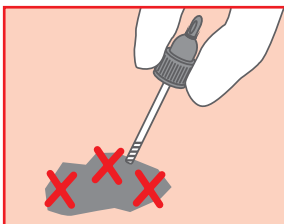
Healthcare professionals with patients who present the following symptoms: heartburn or pain in the upper part of the abdomen, especially in fasting or in the early morning - when the stomach is empty - nausea, reflux, loss of appetite, burping, weight loss and diarrhea.

The test is also indicated to those healthcare professionals who frequently get in touch with potential infected faeces samples to monitor thirself.

TEST PRINCIPLE

HELICOBACTER PYLORI ANTIGEN RAPID TEST is a rapid immunochromatographic lateral flow assay for the detection of *Helicobacter pylori* antigens in human faeces, thanks to special gold conjugate antibodies embedded to a test strip.

HOW TO USE IT



CONTENT: 20 test cassettes; 20 vials with collection stick and diluent; 1 instructions for use leaflet.

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
10 ng/mL	95,20%	96,60%	96,00%

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

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

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
800016P-20P	HELICOBACTER PYLORI ANTIGEN RAPID TEST	20 TESTS	30 MONTHS