



Gastrointestinal



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berkeleyhealth HELICOBACTER PYLORI

Self-test for the determination of anti *Helicobacter pylori* antibodies in whole blood samples



HELICOBACTER PYLORI

Helicobacter pylori (Hp) 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 Hp-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. The simplest way to detect infection is checking the presence of specific antibodies (IgG) produced by the immune system after coming into contact with the bacterium and trying to eliminate it. HELICOBACTER PYLORI TEST can detect the presence of these antibodies in few minutes.

WHO ARE THE INTENDED USERS

Everyone who has gastric symptoms; the most common manifestations of these conditions are heartburn or pain in the upper part of the abdomen, especially when the stomach is empty. Other associated symptoms include nausea, feeling full, reflux, loss of appetite, burping, weight loss and diarrhoea. 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 TEST is an immunochromatographic test that detects the presence of anti-*Helicobacter pylori* IgG antibodies in the blood, using special monoclonal antibodies conjugated with gold and integrated into the reactive strip.

TECH SPECS

CUT-OFF	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
15 AU/mL	95.8%	84.2%	87%

Performance data obtained by clinical study with 100 participants enrolled. IBL ELISA kit has been utilized as reference method.

CONTENT:

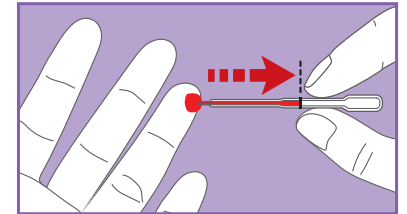
1 sealed aluminium pouch containing: 1 test device and 1 desiccant bag; 1 transparent plastic bag containing a pipette for blood collecting; 1 vial with dropper containing the diluent; 2 sterile lancets for blood sampling; 1 alcohol swab and 1 instructions for use leaflet.

CLINICAL EVIDENCES

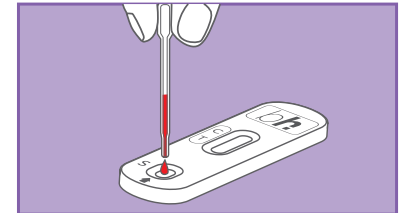
1. Mati Moyat, Dominique Velin. Immune responses to *Helicobacter pylori* infection. *World J. Gastroenterol.* 2014 may 21; 20(19): 5583-5593 IgE." *Journal of Allergy and Clinical Immunology.* 2014;133(2):589-91.
2. Khean-Lee Goh, Wah-Kheong Chan, Seiji Shiota and Yoshio Yamaoka. Epidemiology of *Helicobacter pylori* Infection and Public Health Implications. *Helicobacter*, 2011 Sep;16(01):1-9.
3. Kyichi Adachi, Tomoko Mishiro, Shino Tanaka and Yoshikazu Kinoshita. Analysis of negative result in serum anti-*pylori* IgG antibody test in cases with gastric mucosal atrophy. *J. Clin Biochem Nutr.* 2016 Sep;59(2):145-148.

HOW TO USE IT

1) Take a blood sample after pricking the finger.



2) Deposit the sample into the specimen well of the cassette.



3) Add 2 drops into the well and wait 5 minutes before reading the result.

