

QuickProfile™ H. Pylori Antigen Test Card

Immunochromatographic Rapid Assay For the Detection of *Helicobacter pylori* Antigens

in Human Stool Specimens

Cat.# 71020

For In Vitro Diagnostic Use Only

INTENDED USE

QuickProfile™ H. pylori Antigen Test Card is an *in vitro* qualitative immunochromatographic assay for the rapid detection of *Helicobacter pylori* antigens in human stool specimen. The test results are intended to aid in the diagnosis of *H. pylori* infection, to monitor the effectiveness of therapeutic treatment and to confirm the eradication of *H. pylori* in peptic ulcer patients.

SUMMARY AND EXPLANATION

Helicobacter pylori is a corkscrew-shaped, gram-negative rod that lives in the mucous layer of the stomach. *H. pylori* infection is now accepted as the most common cause of gastritis, and is etiologically involved in gastric ulcer, duodenal ulcer, gastric adenocarcinoma and primary gastric B-cell lymphoma.^{1,2}

The organism is very common, infected at least half of the world's population. *H. pylori* infection is typically acquired in childhood. Once acquired, infection persists chronically, probably continuing in the stomach throughout life. The damage to gastric structure and function of stomach is constant and direct. Approximately one in six of *H. pylori* infection develops peptic ulcer disease and a small portion of *H. pylori* infection leads to gastric cancer.³

The diagnostic tests for *H. pylori* can be classified into two categories: Invasive and Noninvasive tests. Direct detection by invasive test procedures requires an endoscopy and biopsy specimens from antrum and stomach body.⁴ The presence of *H. pylori* is then confirmed by direct culture, histological examination or rapid urease test. The endoscopy and biopsy specimens offer direct detection of active *H. pylori* infections. Although the procedure is highly specific and high positive predictive value, the cost and discomfort to the patients are very high.

The most widely available noninvasive test is probably the serological based test. The serology test detects *H. pylori* specific IgG antibody in patient serum with current or prior infection.^{5,6} Serology test is a simple, convenient test with relative high sensitivity. The main limitation of serology test is the inability to distinguish current and past infections. Antibody may be present in the patient's serum long after eradication of the organism.⁶ The urease breath test (UBT) with ¹⁴C or ¹³C labeled urea, is a noninvasive test based on the urease activity of the organism. UBT detects active *H. pylori* infection and is highly sensitive and specific. The UBT requires a high density and active bacteria and should not be performed until 4 weeks after therapy to allow residual bacterial to increase to a sufficient number for detection.⁷

QuickProfile™ H. pylori Antigen Test is an immune-chromatographic assay that uses antibody-coated colloidal gold to detect the presence of *H. pylori* antigens in stool specimens. The test detects directly antigens in specimens for an active infection. The test is simple and easy to perform and the test results can be visually interpreted within 10 minutes.

PRINCIPLE OF THE ASSAY

QuickProfile™ H. pylori Antigen Test Card is a sandwich solid phase immunochromatographic assay. To perform the test, an aliquot of diluted stool sample is added to the sample well of the test cassette. The sample flows through a label pad containing H. pylori antibody coupled to red-colored colloidal gold. If the sample contains H. pylori antigens, the antigen will bind to the antibody coated on the colloidal gold particles to form antigen-antibody-gold complexes. These complexes move on the nitrocellulose membrane by capillary action toward the test line region on which H. pylori specific antibodies are immobilized. As the complexes reach the test line, they will bind to the antibody on the membrane in the form of a line. A second red control line will always appear in the result window to indicate that the test has been correctly performed and the test device functions properly. If H. pylori antigen is not present or lower than the detection limit of the test, only the control line will be visible. If the control line does not develop, the test is invalid.

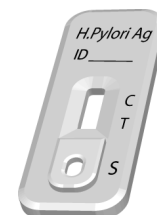
MATERIAL PROVIDED

1. QuickProfile™ H. Pylori Antigen test card

Each cassette contains a test strip with H. pylori specific antibody on the test region of the membrane and colored H. pylori antibody-gold conjugate pad.

2. Sample bottle

Each sample bottle contains 1 ml of stool specimen collection buffer. Store at 4-30°C.



H. Pylori Antigen
Test Card



Sample bottle

MATERIALS REQUIRED BUT NOT SUPPLIED

1. Specimen collection container
2. Timer.

STORAGE AND STABILITY

1. The expiration date is indicated on the package label.
2. Sample Collection Tubes without introducing the sample can be stored at 4-30°C.
3. Test device can be stored at 4-30 °C.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Wear protective glove while handling kit components and test specimens.
3. Patient specimens and inactivated Positive Control may contain infectious agents and should be handled and disposed of as potential biohazards.
4. Do not use kit components beyond expiration date.
5. Dispose all used materials in appropriate container. Treat as potential biohazard.

SPECIMEN COLLECTION AND PREPARATION

Stool specimens should be collected in containers that do not contain media, preservatives, animal serum or detergents as any of these additives may interfere with the QuickProfile™ H. pylori Antigen Test.

Specimens may be stored at 2-8°C for 3 days without interfering with the assay performance. For long-term storage of specimens, -20°C or colder is recommended. Repeated freezing and thawing of specimens is not recommended and may cause erroneous results. Do not store specimens in self-defrosting freezers.

QUALITY CONTROL

1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which is not provided with this test kit may be commercially available.

PROCEDURE

1. Bring all materials and specimens to room temperature.
2. Remove the test card from the sealed foil pouch.
3. Hold the sample bottle upright with the tip point toward the direction away from the test performer, snap off the tip.
4. Hold the bottle in a vertical position over the sample well of the test card, deliver 3 drops (120 -150 µL) of diluted stool sample to the sample well.
5. Read the result within 10 to 15 minutes. A strong positive sample may show result earlier.

Note: Test results after 15 minutes may not be accurate.

INTERPRETATION OF RESULTS

Positive result:

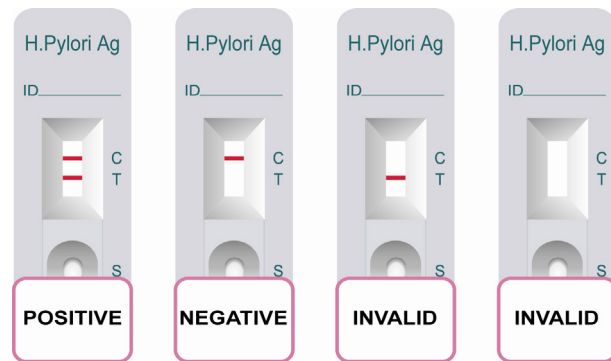
A distinct pink colored band appears on test line regions, in addition to a pink line on the control line region.

Negative result:

No line appears in the test line region. A distinct pink line shows on the control line region.

Invalid:

The control line next to the test line does not become visible within 10 minutes after the addition of the sample.



LIMITATIONS OF THE PROCEDURE

1. The test is for qualitative detection of *H. pylori* antigen in stool sample and dose not indicate the quantity of the antigens.
2. The test is for *in vitro* diagnostic use only.
3. The test result should be used only to evaluate with patient with signs and symptoms of gastrointestinal disease. A definitive clinical diagnosis should only be made by the physician after all clinical and laboratory finding have been evaluated.

EXPECTED VALUES

Helicobacter pylori infects more than half the people in the world.⁹ The prevalence of the infection varies among countries and among different groups within the same country.¹⁰ The prevalence rate in the United State suggests an incidence of infection of 2%. The lifetime prevalence of peptic ulcer disease is about 12% in men and 9% in women.¹¹ Studies have found that more than 90% of patients with duodenal ulcer and 80% of patients with gastric ulcer are infected with *H. pylori*.^{12,13}

QuickProfile™ *H. pylori* Antigen Test Card detects the presence of *H. pylori* antigens in stool specimens. Expected values for any given population should be determined for each laboratory. The positivity rate of any given laboratory may vary depending on geographic location, ethnic group, and living environment.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

QuickProfile™ *Helicobacter pylori* Antigen Test Card was evaluated on 170 adults. The test results were compared to diagnosis of *H. pylori* infection by reference tests, urease breath test and histology tests. Patients were considered positive if both rapid urease and histology tests were positive. Patients with both negative urease breath test and histology tests were considered negative. Among fifty (50) positive samples and one hundred and twenty (120) negative samples, QuickProfile™ *H. pylori* Antigen Test showed 94.0% clinical sensitivity and 96.7% specificity. The accuracy is 97.5%.

QuickProfile™ H.Pylori Antigen Test	Reference Test		
		Positive	Negative
	Positive	47	4
	Negative	3	116

Sensitivity = 94.0% (47/50)

Specificity = 96.7% (116/120)

Positive Predictive Value = 92.2% (47/51)

Negative Predictive Value = 97.5% (116/119)

Accuracy = 95.9% (163/170)

Reproducibility

Reproducibility of QuickProfile™ *H. pylori* Rapid Antigen Test Card was determined using negative, low positive, and high positive samples along with negative and positive controls. These samples were tested in replicates of 8 in a blind study by 5 operators working independently in the same laboratory. The agreement of the expected result was 100%.

Assay Specificity

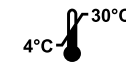
Following bacterial and viral strains were used to test the specificity of QuickProfile™ *H. pylori* Antigen Test. Positive and negative stools were spiked with $>1 \times 10^5$ organism/ml and tested by QuickProfile™ *H. pylori* Antigen Test Card. *H. pylori* positive stool remained positive with the spiked organisms. Negative stool remained negative with the spiked organisms.

Microorganism and virus tested

Adenovirus type II	Campylobacter coli	Campylobacter fetus	Campylobacter jejuni
Campylobacter lari	Candida albicans	Citrobacter freundii	Clostridium difficile
Clostridium perfringens	Enterococcus faecalis	Enterobacter cloacae	Escherichia coli
Escherichia fergusonii	Escherichia hermannii	Helicobacter cinaedi	Helicobacter mustelae
Klebsiella pneumoniae	Mycobacterium smegmatis	Providencia stuartii	Nocardia asteroides
Proteus vul	Pseudomonas aeruginosa	Pseudomonas fluorescen	RotavirusSalmonella(Group B)
Salmonella dublin	Salmonella hilversum(Group N)	Salmonella typhimurium	Salmonella minnesota
Shigella boydii	Shigella dysenteriae	Shigella flexneri	Shigella sonneiSerratia liquefaciens
Staphylococcus aureus	Staphylococcus aureus (Cowan)	Staphylococcus faecalis	Staphylococcus galactiae
Staphylococcus epidermidis	Yersinia enterocolitica		

REFERENCES

1. Marshall, B.J. and Warren, J.R. Unidentified curved bacilli in the stomach of patients with gastric and peptic ulceration. *Lancet* 1984; 1311-1314.
2. Graham K.S and Graham D.Y. 1999. Contemporary Diagnosis and Management of *H. pylori*-Associated Gastrointestinal Diseases, Handbooks in Health Care Co., Newtown, PA., 1999: 39-67.
3. Howden C.W. Clinical expressions of *Helicobacter pylori* infection. *Am J Med*; 1996;100:27S-33S.
4. El-Zimaity HM, Al-Assi MT, Genta RM, Graham DY. Confirmation of successful therapy of *Helicobacter pylori* infection: number and site of biopsies or a rapid urease test. *Am J Gastroenterol*. 1995;90:1962-1964.
5. Talley NJ, Newell DG, Ormand JE, et al. Serodiagnosis of *Helicobacter pylori*: Comparison of enzyme-linked immunosorbent assays. *J. Clin Microbiol*. 1991;29:1635-1639.
6. Cutler AF. Testing for *Helicobacter pylori* in clinical practice. *Am J. Med*. 1996;100:35S-41S.
7. Klein PD, Malaty HM, Martin RF, et al. Noninvasive detection of *Helicobacter pylori* infection in clinical practice: the ¹³C urea breath test. *Am J. Gastroenterol*. 1996;91:690-694.
8. National Committee for Clinical Laboratory Standards. Internal quality control: Principles and definitions; Approval Guideline, NCCLS document C24-A (NCCLS, 771 East Lancaster Ave, Vallanova, PA 19085, 1991).
9. Marshall BJ. *JAMA*. 1995;274:1064-1066
10. Breuer T, Malaty HM, Graham DY. The epidemiology of *H. pylori*-associated gastroduodenal diseases. In: Ernst PB, Michetti P, Smith PD, eds. The Immunobiology of *H. pylori*: From Pathogenesis to Prevention. Philadelphia. Lippincott-Raven, 1997:1-14.
11. Graham DY, Malaty HM, Evans DG, Evans, Jr. DJ, Klein PD, and Adam E. Epidemiology of *Helicobacter pylori* in a asymptomatic population in the United States. Effect of age, race, and socioeconomic status. *Gastroenterology*, 1991;100:1495-1501.
12. Anand BS, Raed AK, Malaty HM, et al. Low point prevalence of peptic ulcer in normal individual with *Helicobacter pylori* infection. *Am J Gastroenterol*. 1996;91:1112-1115.
13. Tytgat GNJ, Noach LA, Rauws EAJ. *Helicobacter pylori* infection and duodenal ulcer disease. *Gastroenterol Clin North Am*. 1993;22:27-139.



LumiQuick Diagnostics, Inc.
2946 Scott Blvd.
Santa Clara, CA 95054 USA
Tel : (408) 855.0061
Fax: (408) 855.0063
Email: info@lumiquick.com
www.lumiquick.com

Emergo Europe
Molenstraat 152513 BH The Hague
The Netherlands
Tel: +31(0)70.345.8570
Fax: +31(0)70.346.7299