



Significance of High Sensitivity *Helicobacter pylori* Rapid Test Cassette for Prevention and Treatment of Gastrointestinal Diseases

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Abstract

Aim: *Helicobacter pylori* (*H. pylori*) is a Gram-negative, spiral, microaerophilic, flagellated bacterium that can change its shape from spiral to coccidial and is thought to be associated with enhanced bacterial survival in the host gastric microenvironment. The spiral form of *H. pylori* allows for successful bacterial motility, while the coccidial form provides the ability to colonize the mucus layer of the gastric epithelium, further enhancing bacterial invasiveness. Among all the microorganisms some are very much fatal to humans and among them *H. pylori* is one of the most common infectious pathogens frequently causing imbalance in the health of humans in the world, and its infection can lead to wide range of gastrointestinal diseases. Research is ongoing and some studies shown that *H. pylori* is the major reason for occurrence of chronic gastritis, most probably active gastritis which is the direct, indirect reason and closely related to peptic ulcer and it is also one of the factors for the gastric ulcers formation. *Helicobacter pylori* is a common strain of gastrointestinal bacteria which is plays a major role in the incidence of chronic gastritis, peptic ulcers, gastric mucosa-associated lymphoid tissue lymphoma and gastric cancer. Currently, Gastric cancer has become one of the most common malignancies where men and women are easily prone to and additionally, it is the fourth most common reason for cancer-related fatalities globally. The interplay of hereditary and environmental variables, of which *H. pylori* infection is the most significant, is linked to the development of stomach cancer. Its been more than 20 years in discovering the strain of *H. pylori*, and currently it became highly resistant and is infecting more than half of the world's population. For gastroenterologists, research on *H. pylori* infection has long been crucial. *H. pylori* antibody rapid test cassette (serum/plasma) is the test used to study the human gastrointestinal conditions, particularly those affecting those with gastric cancer.

Objective: The main purpose of this evaluation report is to explore the auxiliary significance of *H. pylori* antibody rapid test cassette (serum/plasma) in the study of human gastrointestinal diseases, especially gastric cancer patients.

Methods: A rapid *in vitro* diagnostic test devise is used for detecting the presence of IgG antibodies that are released against *Helicobacter pylori* virus in serum or blood plasma and comparison was made with a leading commercial *H. pylori* antibody ELISA test for validating the performance.

Results: The overall relative sensitivity results of *H. pylori* shown that the primary and secondary infection rate upon performing *H. pylori* antibody rapid test cassette (serum/plasma) is 95.5%, the relative specificity is 91.3%, and the relative accuracy is 93.7%.

Conclusion: To prove that the new antibody detection method is the most useful ideal test for qualitative analysis of antibodies that are present in blood plasma or serum is *H. pylori* antibody rapid test cassette (serum/plasma) where the results of the groups are compared with the C-urea breath test which is used as the standard for diagnosing the infection ratio of *Helicobacter pylori* and finally attained both high specificity and sensitivity. The diagnostic accuracy of the *H. pylori* antibody rapid test cassette was 92.0%, sensitivity was 92.3%, specificity was 91.7%, positive predictive value was 92.3%, and the negative predictive value was 91.7%. This study is compared with gastroscopy too where the *H. pylori* antibody rapid test cassette is a non-invasive test. Finally, we believe that the better diagnostic method for the detection of current *H. pylori* infection is performed through *H. pylori* antibody rapid test cassette and it comprises all the characteristics of application, convenience and patient compliance.

Keywords: *Helicobacter pylori*; Gastritis; Gastrointestinal diseases; Gastric mucosa

Introduction

About *Helicobacter pylori*

H. pylori are a kind of spiral, micro aerobic bacteria that requires very strict growth conditions. In 1983, it was successfully isolated from gastric mucosa biopsy tissue of patients with chronic active gastritis for the first time. It is the only microbial species that can survive in human stomach. Since 1994, Organizations like International Agency for Research on Cancer and World health Organization officially classified this *Helicobacter pylori* as the class I cancer causing agent which is the major reason for the onset of gastric cancer. The colonization of gastric mucosa with *Helicobacter pylori* pathogen has been experienced by nearly half of the world population where the individuals are remained asymptomatic in most of the cases [1,2].

The prevalence of the infections induced by *H. pylori* is estimated at 85%-95% in developing countries and approximately 30%-50% in developed countries [3,4]. The oral-to-oral and fecal-to-oral routes are two major transmission routes of the bacterium. The adaptation mechanisms of *H. pylori* include the bacterial and environmental factors that enable its survival in the gastric microenvironment where the acidity is at pH even lower than 3.0 [5,6]. The pathogenicity of *H. pylori* is associated with several mechanisms, among which the alterations of the host signaling pathways, indirect inflammatory responses induced within the gastric mucosa, and direct epigenetic outcomes on gastric epithelial cells, are of major importance [7].

Materials and Methods

Diseases and symptoms caused by *H. pylori*

The major symptoms involved in *Helicobacter pylori* infection are acid regurgitation, heartburn, stomach ache and bad breath. The reason behind all these symptoms are *H. pylori* that induces the rapid secretion of gastrin, finally leading to heartburn. In patients with gastric ulcer disease, the main symptom would be of stomach pain and the bad breath is due to direct release of germs of *H. pylori*. *H. pylori* a pathogenic bacterium and causes gastrointestinal diseases, including chronic gastritis. The main clinical manifestations are epigastric discomfort, dull pain, sometimes belching, acid regurgitation, nausea and vomiting. The course of the disease is relatively slow but is able to relapse easily. *H. pylori* infection usually has no obvious symptoms. At this time, it is generally determined by inspection.

Prevention and diagnosis of *H. pylori*

Prevention methods: *H. pylori* positive patients should seek medical treatment when known. Once stomach symptoms are controlled, the chance of continuing to infect others is greatly reduced. For *H. pylori* positive people, it is strongly recommended that family members test to avoid cross-infection, resulting in repeated infection. To control and prevent *H. pylori*, it is necessary to cut off the transmission route and pay close attention to personal hygiene, oral hygiene, diet, and pay special attention to disinfection of tableware and chopsticks, and not share them. *H. pylori* enter the human body through the mouth as the bacteria are often present in the tartar and saliva of patients and carriers. Therefore, paying attention to oral hygiene and preventing disease from entering from the mouth are

important measures to prevent *H. pylori*, infection, gastric disease and gastric cancer.

***H. pylori* diagnostic methods:** *H. pylori* infection can be diagnosed several ways. Depending on the patient's symptoms and the timing of the doctor's visit, different diagnostic methods may be appropriate.

Breath test/urea breath test: The *H. pylori* Breath test is one of the most advanced equipment for the detection of *H. pylori* which will detect the infectious cases of *H. pylori* without intubation.

Direct inspection of bacteria: The direct method to detect *Helicobacter pylori* is gastroscopy forceps where direct smear of gastric mucosa taken for staining, tissue section staining and bacterial culture.

Rapid chromatographic immunoassay: Here the Detection of *H. pylori* infection can be done by measuring *H. pylori* antibodies in serum. The *H. pylori* Antibody Rapid Test Cassette (serum/plasma) can be used for screening.

Results and Discussion

Evaluation of citest *H. pylori* antibody rapid test cassette (serum/plasma)

Materials and directions for use: Materials provided included a test cassette, droppers, and package insert. The qualitative membrane based immunoassay used for the detection of *H. pylori* antibodies in serum or plasma is *H. pylori* antibody rapid test cassette (serum/plasma). In this test procedure, anti-human IgG is immobilized in the test line region of the test. After specimen is added to the specimen well of the cassette, it reacts with *H. pylori* antigen coated particles in the test. This mixture migrates chromatographically along the length of the test and interacts with the immobilized anti-human IgG. If the specimen contains *H. pylori* antibodies, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain *H. pylori* antibodies, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred. In serum and plasma assays, first bring the bag to room temperature (15°C-30°C) before opening and remove the test cassette from the sealed bag and use within one hour.

For serum or plasma specimens: Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.

Using the dropper: Hold the dropper vertically and transfer 3 drops of serum or plasma (approximately 75 µL) to the test cassette specimen well and start the timer. Avoid trapping air bubbles in the specimen well. Then wait for the colored line to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

Performance characteristics: The *H. pylori* antibody rapid test cassette (serum/plasma) has been evaluated with serum and plasma specimens obtained from a population of symptomatic and asymptomatic individuals who presented for endoscopic examination (Table 1).

Method: <i>H. pylori</i> antibody rapid test cassette (serum/plasma)			
ELISA			Total
Results	Positive	Negative	Results
Positive	211	14	225
Negative	10	146	156
Total Results	221	160	381

Table 1: Results obtained upon performing *H. pylori* antibody rapid test cassette (serum/plasma).

Relative sensitivity: 95.5% (95%CI*:91.8%-97.8%)

Relative specificity: 91.3% (95%CI*:85.7%-95.1%)

Overall accuracy: 93.7% (95%CI*:90.8%-95.9%)

Expected values: The *H. pylori* antibody rapid test cassette (serum/plasma) has been compared with a leading commercial *H. pylori* antibody EIA test. The correlation between these two systems is 93.7%.

Conclusion

At present, *H. pylori* positive cases are closely related to the occurrence of gastric mucosa associated lymphoid tissue, upper gastrointestinal ulcer, chronic gastritis and gastric cancer. Therefore, during physical examinations, targeted treatment should be given, which is of great significance for the prevention and treatment of diseases related to *H. pylori*.

In the detection of *H. pylori*, methods include serological detection, urease antibody detection, and 14C urea breath test, which are routine methods for clinical detection of *H. pylori*. Compared with other conventional detection methods, the citest rapid detection kit is easy to operate and non-invasive and does not require patients to go through routine gastroscopy. Therefore, rational selection of non-invasive *H. pylori* detection methods according to different patients and different treatment stages can provide timely treatment and monitor the evolution of the disease course and provide timely information and services for clinical work.

The Citest rapid detection kit has the characteristics of high sensitivity and good accuracy. The test has great significance for primary screening of *H. pylori* and has a positive impact on the prevention and control of gastrointestinal diseases. The authors conclude that it is necessary to add *H. pylori* testing to middle-aged people for health examination. Early detection and treatment can reduce transmission of *H. pylori* and improve patients' quality of life. This practice is worth popularizing and creating awareness.

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