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Evaluation of the Performance Characteristics of *H. pylori* Antibody Rapid Test for Point-of-Care Diagnosis

Zhang Lei[1*], Yang Feng[2] and Zhu Junzhe[3]

[1]*Department of Nursing Sciences, Zhejiang Gongshang University, Hangzhou, China*

[2]*Community Health Service Center, Hangzhou, China*

[3]*Department of Nursing Sciences, Wenzhou Medical University, Wenzhou, China*

[*]**Corresponding author:** Dr. Zhang Lei, Department of Nursing Sciences, Zhejiang Gongshang University, Hangzhou, China, E-mail: zhanglei@zjgsu.edu.cn

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Abstract

Helicobacter pylori, a spiral-shaped bacterium, predominantly inhabits the human gastric mucosa. Recognized as a primary causative agent in gastritis, gastric ulcers, and gastric cancer, *H. pylori* comprises the gastric mucosa's protective layer *via* its enzymatic and toxic activities, precipitating inflammation and tissue damage. Given these implications, early and accurate diagnosis, followed by intervention, is paramount to curb the spread of this infection. This study evaluates the *H. pylori* Antibody Rapid Test's diagnostic precision in identifying *Helicobacter pylori* infection is evaluated

This rapid immunoassay utilizes chromatography to qualitatively detect *H. pylori* in human whole blood, serum, or plasma. Its effectiveness is assessed in comparison to established standards such as biopsy, histology, and the Rapid Urease Test (RUT), with results demonstrating its excellent diagnostic capabilities. The test validated a sensitivity of 96.8% and a specificity of 93.0% when compared to results obtained from Biopsy/Histology/RUT. As a reliable diagnostic tool, the *H. pylori* Antibody Rapid Test facilitates the swift detection of *H. pylori* infection, expediting the commencement of treatment, reducing the transmission of *Helicobacter pylori*, and guiding treatment decisions. These performance evaluations underscore its potential to refine clinical approaches, improve patient health outcomes, and enhance their quality of life. In the realm of *H. pylori* infection diagnosis, the *H. pylori* Antibody Rapid Test stands as a valuable tool, offering convenience, efficiency, and dependable results. Its integration into clinical practice can significantly contribute to early detection and management of *H. pylori* infection, ultimately leading to enhanced patient outcomes and a reduction in the burden of *H. pylori*-related gastric diseases.

Keywords: *H. pylori*; Rapid test; RUT; Biopsy; Histology

Introduction

Helicobacter pylori

Helicobacter pylori (*H. pylori*) is a Gram-negative bacterium that predominantly colonizes the human stomach. It was notably identified in 1982 by Australian scientists Barry J. Marshall and Robin Warren. The spiral-shaped bacterium boasts multiple flagella, enabling it to navigate the mucus layer and anchor itself to the epithelial cells lining the stomach. Remarkably adopted to the stomach's acidic milieu, *H. pylori* can persist and flourish in this environment for extended periods. The prevalence of *H. pylori* infection is concerning, with estimates indicating that it impacts approximately half of the world's population [1]. This infection is associated with various health conditions, including chronic gastritis and peptic ulcers, as well as more severe conditions such as gastric cancer and Mucosa-Associated Lymphoid Tissue (MALT) lymphoma. Furthermore, it has ties to extragastric disorders, such as atherosclerosis and specific skin lesions [2]. Thus, heightening awareness, endorsing early detection, and facilitating apt treatment are essential steps towards blunting health impacts of this infection.

Diagnosis

Diagnostic approaches for *H. pylori* infection are multifaceted, with an array of tests with varying precision and sensitivity. Typically, these tests are bifurcated into direct (invasive) and indirect (noninvasive) categories [3].

The non-invasive suite of tests for detecting *H. pylori* infection include the carbon urea breath test, stool antigen test, and the blood antibody test. The carbon urea breath test necessitates the patient to consume a particular substance, typically urea labeled with 14C or 13C isotopes. Upon metabolism by *H. pylori*, this substrate transmutes into isotope-labelled carbon dioxide, which is subsequently detectable in exhaled breath. The stool antigen test, in contrast, identifies *H. pylori* antigens present in fecal samples. Meanwhile, the blood antibody test quantifies antibodies targeting *H. pylori* in the circulatory system. These non-invasive tools offer a convenient avenue for the diagnosis, promoting prompt recognition and management of the infection.

Invasive diagnostic methods come into play during an upper gastrointestinal endoscopy. Here, biopsy is employed, wherein tissue

samples from the gastric lining are harvested and then subjected to a spectrum of tests. These might include histology, the Rapid Urease Test (RUT), or Polymerase Chain Reaction (PCR). Histology assessments involved a microscopic probe into tissue samples to spot of *H. pylori* entities. The RUT capitalizes on a unique solution to ascertain the presence of urease–an enzyme intrinsic to *H. pylori*. The PCR technique, a molecular powerhouse, is leveraged to amplify and detect *H. pylori* DNA nestled within the biopsy specimens. These invasive methods confer detailed insights, bolstering the precision of diagnoses and shaping treatment trajectories.

Deciding on the optimal diagnostic avenue is contingent on a mosaic of factors. These encompass the test's sensitivity, specificity, economic considerations, accessibility, reliability, inherent limitations, the clinical backdrop, infection prevalence within the community, and the pretest likelihood of infection [4].

Prevention

Given the significant health implications associated with *H. pylori*, especially its ties to specific cancers and burgeoning antibiotic resistance, the importance of curbing its transmission cannot be overstated. Although there have been promising strides towards formulating vaccines that could serve as an alternative strategy against *H. pylori*, tangible progress in clinical trials remain elusive, and major pharmaceutical entities have largely sidelined it from their priority list [5].

Nevertheless, there are proactive measures individuals can adopt to reduce the risk of infection:

- Good hygiene practices, such as meticulous handwashing, especially prior to meals and following restroom use, is vital to avert contact with the bacteria.
- Ensuring the consumption of thoroughly cooked meals, particularly shellfish, and drinking purified water can thwart infection.
- Safe intimate practices and minimizing exposure to infected individuals can curtail transmission risk.

On the treatment front, antibiotic therapies have shown promise in ousting *H. pylori* during its nascent infection stages. While there exists a divergence of opinions regarding these treatments staving off advanced histopathological anomalies and gastric adenocarcinoma, there's consensus on their efficacy in dampening inflammation and lowering instances of subsequent *H. pylori*-related gastric adenocarcinoma [6-9].

Materials and Methods

Evaluation of AllTest *H. pylori* antibody rapid test

Objective: The primary aim of this assessment report was to evaluate the dependability and effectiveness of the *H. pylori* Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) for the swift detection of *H. pylori* infection.

Method: The *H. pylori* Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) underwent a thorough evaluation using samples collected from a diverse cohort, including individuals with both symptomatic and asymptomatic presentations who were scheduled for endoscopic examination.

Principle: The *H. pylori* Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) employs a qualitative membrane-based immunoassay to detect *H. pylori* antibodies in samples of whole blood, serum, or plasma. In this testing process, anti-human IgG is affixed to the test line region of the cassette. Once a specimen is introduced into the specimen well of the device, it engages with *H. pylori* antigen-coated particles within the test. This mixture then chromatographically traverses the test's length and interacts with the immobilized anti-human IgG. The presence of *H. pylori* antibodies in the specimen generates a colored line in the test line region, signifying a positive result. Conversely, if the specimen lacks *H. pylori* antibodies, no colored line will emerge in this region, indicating a negative outcome. To ensure the procedural accuracy, a colored line will consistently materialize in the control line region, confirming the appropriate specimen volume addition and successful membrane wicking.

Directions for use: Before conducting the test, ensure that the test kit, specimen, buffer, and/or controls are allowed to equilibrate to room temperature (15-30˚C). Also, let the pouch attain room temperature before unsealing it. Once ready, extract the test cassette from the sealed pouch and utilize it promptly. Position the cassette on a clean, flat surface.

For serum or plasma specimen: Gently hold the dropper in a vertical position and dispense 3 drops of whole blood (about 75 µL) into the specimen well. Next, introduce 1 drop of buffer (approximately 40 µL), and commence the timer.

For venipuncture whole blood specimen: Load the capillary tube with approximately 75 µL of fingerstick whole blood specimen, and gently transfer it to the specimen area on the test cassette. Following this, dispense 1 drop of buffer (approximately 40 µL), and initiate the timer.

For fingerstick whole blood specimen: Allow 3 hanging drops of fingerstick whole blood specimen (around 75 µL) to descend into the specimen area of the test cassette. Afterward, introduce 1 drop of buffer (approximately 40 µL), and start the timer. Observe for the appearance of colored lines. Results should be read at the 10-minute mark, and it is essential not to interpret the result after 20 minutes. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the result after 20 minutes.

Results and Discussion

Performance characteristics

The *H. pylori* Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) underwent thorough assessment using samples collected from both symptomatic and asymptomatic individuals who were undergoing endoscopic examinations. The reference method employed in these evaluations was the Biopsy (Culture) technique served as the reference. For specimens that tested negative *via* the Culture method, additional assessments were carried out through Histology and the Rapid Urease Test (RUT). A specimen was designated as positive in cases where the culture was confirmed positive. In instances where the culture was negative, a concurrent positive result from both Histology and RUT rendered the specimen positive. Results from the study revealed that the *H. pylori* Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) achieves a sensitivity of 96.8% and a specificity of 93.0% benchmarked against the combined results of Biopsy, Histology and RUT (Table 1).

Method		Biopsy/ Histology/RUT	Total	
H. pylori rapid	Results	Positive	Negative	Results
Test cassette	Positive	150	15	165
	Negative	5	200	205
Total results		155	215	370

Table 1: *H. pylori* antibody rapid test cassette *vs*. biopsy/histology/RUT.

Relative Sensitivity: 96.8% (95%CI*: 92.6%-98.9%); *: Confidence Interval

Relatively Specificity: 93.0% (95%CI*: 88.8%-96.0%)

Accuracy: 94.6% (95%CI*: 91.8%-96.7%)

Expected values

In comparative evaluations with Culture and Histology, the *H. pylori* Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) delivered an overall accuracy of 94.6%.

Empirical comparisons with Biopsy/Histology/RUT underscore that the *H. pylori* Antibody Rapid Test developed by Hangzhou AllTest Biotech Co., Ltd. meets expectations and exhibits high specificity, sensitivity, and accuracy. This Rapid Test offers the advantages of user-friendliness and reliability. Its design eliminates the need for specialized laboratory infrastructure or trained personnel, and it delivers quick results within a 15-minute window.

However, it is important to acknowledge the limitations of this study. The *H. pylori* Antibody Rapid Test Cassette (Whole Blood/Serum/Plasma) is designed exclusively for *in vitro* diagnostic purposes, specifically for the detection of *H. pylori* antibodies in specimens of whole blood, serum, or plasma. It is important to note that this qualitative test cannot provide the quantitative value or rate of increase in *H. pylori* antibody concentration.

As with any diagnostic tests, it is crucial to analyze the outcomes of the *H. pylori* Antibody Rapid Test Cassette alongside other available clinical data in consultation with a healthcare professional. In cases where the test yields a negative result but clinical symptoms persist, it is advisable to pursue further examination through alternative clinical methodologies. It's important to bear in mind that a negative result does not entirely exclude the potential of *H. pylori* infection at any point. Hence, a thorough assessment that takes into account all clinical factors is essential for precise diagnosis and suitable medical care.

Conclusion

The results obtained from sample analysis indicate that the *H. pylori* Antibody Rapid Test by Hangzhou AllTest Biotech Co., Ltd. fulfills the stringent requirements set for *in vitro* professional diagnostic use. This tool stands as a reliable asset for the rapid detection and diagnostic aid in identifying *Helicobacter pylori* infections. Its incorporation into medical practice bolsters the precision and speed in diagnosing *H. pylori* infections, thereby empowering healthcare professionals to devise well-informed therapeutic strategies and offer prompt patient care.

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