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User-Friendly Self-Testing Evaluation of H. Pylori Antigen Detection in Feces

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Abstract: The H. pylori Antigen Rapid Test Cassette (Feces) is a chromatographic immunoassay developed for the qualitative detection of Helicobacter pylori (H. pylori) antigens in human fecal specimens. This research intends to conduct a systematic assessment of its performance metrics, such as sensitivity, specificity, accuracy and clinical applicability, in comparison with another commercial rapid test. A total of 180 fecal samples were tested, consisting of 85 H. pylori antigen-positive and 95 H. pylori antigen-negative specimens. The outcomes revealed high relative sensitivity 97.6%, 95%, specificity 97.9% and overall accuracy 97.8%. The test exhibited no cross-reactivity with various common bacteria and viruses, along with excellent intra-assay and inter-assay precision, achieving over 99% correct identification of samples. These results suggest that the H. pylori Antigen Rapid Test Cassette (Feces) is a reliable, rapid, and practical tool for detecting H. pylori antigens, which can facilitate the timely diagnosis and management of H. pylori-related gastrointestinal diseases.

1. Introduction

Helicobacter pylori (H. pylori) is a spiral-shaped bacterium that colonizes the gastric mucosa and plays a significant role in the development of various gastrointestinal disorders, including gastritis, peptic ulcers and even gastric cancer [1]. The high global prevalence of H. pylori infection underscores the importance of accurate and timely diagnosis for effective patient care [2].

Traditional diagnostic approaches for H. pylori include invasive procedures like gastric biopsy with histology, urease testing, or culture. These methods are not only uncomfortable for patients but also demand specialized equipment and trained personnel [3]. Non-invasive methods, such as serological testing for antibodies, have drawbacks as they cannot differentiate between current and past infections[4]. In recent years, stool antigen testing has emerged as a promising non-invasive alternative, offering convenience and the capability to detect active infections.

The H. pylori Antigen Rapid Test Cassette (Feces) is a chromatographic immunoassay that delivers results within 10 minutes, making it suitable for point-of-care settings, including self-testing. However, a comprehensive evaluation of its performance is necessary to validate its

clinical value. This study aims to assess the diagnostic performance of the H. pylori Antigen Rapid Test Cassette (Feces) using clinical fecal samples, with another commercial rapid test as the reference method, and to discuss its potential role in clinical practice.

2. Materials and Methods

2.1 Specimen Collection

A total of 180 fecal samples were collected, including 85 H. pylori antigen-positive and 95 H. pylori antigen-negative specimens. All specimens were stored properly and brought to room temperature (15-30 ℃) before testing, following standard procedures to ensure sample integrity.

The test kit used was the H. pylori Antigen Rapid Test Cassette from Hangzhou AllTest Biotech Co., Ltd. The reference method was ABON's HPG Rapid Test, a commercial rapid test for H. pylori antigen detection.

2.2 Test Kit and Procedure

The test was conducted following the guidelines provided in the H. pylori Antigen Rapid Test Cassette package insert. Initially, the fecal specimens were brought to room temperature (15-30 ℃). The test cassette was placed on a clean, flat surface, and 80μL of the diluted specimen was added to the sample well. A timer was started immediately after adding the sample. Results were assessed at 10 minutes, with no readings taken after 20 minutes.

A positive result is indicated by the appearance of two colored lines, one in the Test line (T) and one in the Control line (C) regions, confirming the presence of H. pylori antigen in the feces, which necessitates consultation with a healthcare provider. It's important to note that the intensity of the color in the Test line (T) may vary based on the concentration of H. pylori antigen; thus, any visible color in this area should be interpreted as positive. A negative result is shown by a single colored line in the Control line (C) with no line in the Test line (T), indicating that H. pylori antigen was not detected in the sample. An invalid result occurs when the Control line does not appear, which may be due to insufficient sample volume or improper test procedures. In such cases, the testing process should be reviewed, and the test should be repeated using a new kit. If issues continue, it is advisable to stop using the test kit and contact the local distributor.

3. Results and Discussion

3.1 Performance Characteristics

3.1.1 Sensitivity, Specificity, and Accuracy

Table 1: Diagnostic performance of the H. pylori Antigen Rapid Test Cassette compared to Other Rapid Test

Method		Other Rapid Test		Total
H. pylori Antigen Rapid Test Cassette	Results	Positive	Negative	
	Positive	83	2	85
	Negative	2	93	95
Total Results		85	95	180

Relative Sensitivity: 97.6%. Relative Specificity: 97.9%. Overall accuracy: 97.8%

The H. pylori Antigen Rapid Test Cassette (Feces) was evaluated using samples from both symptomatic and asymptomatic individuals. The results showed that the sensitivity of the H. pylori

Antigen Rapid Test Cassette (Feces) was 97.6% and the specificity was 97.9% relative to other rapid tests. The result analysis is presented in table 1.

3.1.2 Cross-reactivity and Interference

To ensure the specificity and reliability of the H. pylori Antigen Rapid Test Cassette, thorough evaluations of cross-reactivity and potential interference were conducted. For the cross-reactivity assessment, a panel of common microorganisms was tested at a high concentration of 1.0E+09 organisms/ml. This panel included Acinetobacter calcoaceticus, Acinetobacter spp., Branhamella catarrhalis, Candida albicans, Chlamydia trachomatis, Enterococcus faecium, E. coli, Enterococcus faecalis, Gardnerella vaginalis, Group A, B, and C Streptococcus, Haemophilus influenzae, Klebsiella pneumoniae, Neisseria gonorrhoeae, Neisseria meningitidis, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Rotavirus, Salmonella choleraesius, Staphylococcus aureus, and Adenovirus. The test did not yield positive results for any of these organisms, thereby confirming that the assay specifically detects H. pylori antigens without cross-reacting with other prevalent pathogens.

In terms of interfering substances, various compounds that may be present in fecal samples were tested at relevant concentrations. These substances included ascorbic acid (20 mg/dL), oxalic acid (60 mg/dL), bilirubin (100 mg/dL), uric acid (60 mg/dL), aspirin (20 mg/dL), urea (2000 mg/dL), glucose (2000 mg/dL), caffeine (40 mg/dL), and albumin (2000 mg/dL). The presence of these substances did not affect the test results, as the assay correctly identified positive and negative samples in their presence. This indicates that the test is robust and less likely to produce false results due to common interfering compounds in clinical samples.

3.1.3 Precision

Intra-assay precision: All 15 replicates of each sample type (negative, low titer positive, middle titer positive, high titer positive) were correctly identified, resulting in >99% accuracy.

Inter-assay precision: Across three different lots, 15 independent assays for each sample type also showed >99% correct identification, demonstrating excellent reproducibility.

3.2 Discussion

3.2.1 Clinical Implications

The high sensitivity and specificity of the H. pylori Antigen Rapid Test Cassette make it a valuable tool in clinical practice. Its rapid turnaround time (results available in 10 minutes) allows for timely diagnosis, which is crucial for initiating appropriate treatment promptly. This is particularly important given the association of H. pylori with various gastrointestinal diseases, where early intervention can improve patient outcomes.

Compared to invasive methods, the test uses fecal specimens, which are non-invasive and easier to collect, increasing patient compliance, especially in pediatric and elderly populations. Additionally, its simplicity and portability make it suitable for use in various settings, including clinics, primary care offices, and even resource-limited areas.

3.2.2 Limitations

Although the test demonstrates strong performance, it has several limitations. Firstly, it is a qualitative assay, which means it does not provide quantitative data on antigen concentration—information that is crucial for monitoring treatment effectiveness. Additionally,

false negative results may occur, especially when antigen levels drop below the detection threshold, such as during antibiotic therapy when H. pylori levels can be significantly reduced. The accuracy of the test is also dependent on proper sample collection, handling, and strict adherence to the testing protocol; any deviations, like incorrect sample dilution or reading results outside the recommended timeframe, can lead to inaccuracies. Furthermore, while the risk is low, false positive results may occur due to immunological cross-reactivity with untested substances, although this issue was not noted in the assessed organisms.

3.2.3 Comparison with Other Diagnostic Methods

The H. pylori Antigen Rapid Test Cassette (Feces) offers distinct advantages when compared to other diagnostic methods for H. pylori detection. In contrast to invasive methods such as gastric biopsy with histology, urease testing, or culture, which require specialized medical procedures and equipment, this test utilizes fecal samples, making it non-invasive and more accessible for patients, including children and individuals with anxiety related to medical procedures. The invasive methods also involve longer processing times and higher costs, whereas the rapid test provides results within 10 minutes, enabling immediate clinical decision-making.

Compared to serological tests that detect antibodies against H. pylori, the rapid stool antigen test has a key advantage in distinguishing active infections from past exposures. Serological tests often remain positive even after successful eradication of H. pylori, as antibodies can persist for months or years, leading to potential misdiagnosis. In contrast, the H. pylori Antigen Rapid Test Cassette targets antigens present in feces, which correlate with active infection, making it more suitable for both initial diagnosis and post-treatment monitoring.

When compared to the reference method used in this study, ABON's HPG Rapid Test, the H. pylori Antigen Rapid Test Cassette demonstrates comparable performance in terms of sensitivity (97.6% vs. reference method's established performance) and specificity (97.9% vs. reference method's established performance). This equivalence supports its reliability as an alternative rapid testing option. Additionally, the test's ease of use—requiring only basic sample handling and no specialized training—makes it more adaptable to point-of-care settings, such as primary care clinics, resource-limited environments, or at home, where complex diagnostic equipment may not be available.

4. Conclusion

The H. pylori Antigen Rapid Test Cassette (Feces) has demonstrated impressive performance metrics, with a sensitivity of 97.6%, specificity of 97.9%, and an overall accuracy of 97.8% when compared to a commercial reference method. It exhibits excellent precision, shows no cross-reactivity with common pathogens, and is unaffected by typical interfering substances.

This test offers rapid results, requires non-invasive sample collection, and is user-friendly, making it a practical choice for diagnosing H. pylori infections in clinical environments. However, it is important to interpret the results alongside clinical symptoms and other relevant data. In cases where a negative result is obtained but there is a strong clinical suspicion, further testing may be warranted.

In summary, the H. pylori Antigen Rapid Test Cassette is a valuable tool in the diagnostic arsenal for H. pylori detection, enhancing patient care through timely and accurate diagnosis.

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