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

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ABSTRACT

The Helicobacter pylori Antigen Rapid Test Cassette (Feces) is a chromatographic immunoassay designed for qualitative detection of H. pylori antigens in human fecal specimens. This study evaluated its performance using 180 fecal samples (85 positive, 95 negative) compared to a commercial reference test. Results showed high sensitivity (97.6%), specificity (97.9%), and accuracy (97.8%). No cross-reactivity or interference was observed with common pathogens or compounds, and intra-/inter-assay reproducibility exceeded 99%. These findings confirm the assay's clinical utility as a rapid, reliable, and user-friendly diagnostic tool for H. pylori detection.

Keywords

Helicobacter pylori; Antigen Rapid Test; Fecal Specimen; Chromatographic Immunoassay; Gastrointestinal Diseases

INTRODUCTION

Helicobacter pylori is a spiral-shaped bacterium that colonizes the gastric mucosa and contributes to gastritis, peptic ulcers, and gastric cancer. Accurate and timely detection is essential. Traditional invasive methods, such as biopsy and culture, are resource-intensive and uncomfortable. Serological tests cannot distinguish active from past infections. Stool antigen testing offers a non-invasive, rapid alternative. This study evaluates the diagnostic performance of the H. pylori Antigen Rapid Test Cassette (Feces) compared with another rapid test.

CONTENT

Materials and Methods

- Specimen Collection: 180 fecal specimens (85 positive, 95 negative) were collected.
- Test Procedure: Evaluated kit (AllTest Biotech, Lot: HPG15090001-T) vs. ABON's HPG Rapid Test (reference). 80 µL of diluted specimen applied; results read at 10 minutes.
- Interpretation: Positive (T+C lines), Negative (C line only), Invalid (no C line).

Results

- Diagnostic Performance: Sensitivity 97.6%, Specificity 97.9%, Accuracy 97.8%.
- Cross-reactivity: None with 20+ microorganisms (e.g., E. coli, C. albicans, S. aureus).
- Interference: No effect from bilirubin, uric acid, caffeine, glucose, etc.
- Precision: >99% reproducibility in intra- and inter-assay testing.

Discussion

- Clinical Implications: Rapid, non-invasive, and patient-friendly. Especially useful in pediatrics, elderly, and

low-resource settings.
- Limitations: Qualitative only; possible false negatives during antibiotic use; dependent on proper handling.
- Comparison with Other Methods: More practical than invasive biopsy; superior to serology for distinguishing active infection; comparable to ABON's rapid test in performance.

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