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Comparison Study of Diaspot Rapid One Test and Advanced Quality Test in the Diagnosis of H. Pylori from Smokers

Lamyaa Gh. Fejer[1*]
[1] College of Pharmacy, Mustansiriyah University, Iraq

Email: lamyaagh@uomustansiriyah.edu.iq

Abstract. Background :Helicobacter pylori is a microaerophilic, gram-negative bacterium that colonizes the human gastrointestinal tract and represents one of the most widespread bacterial infections globally. Several studies have shown a strong correlation between smoking and increased susceptibility to H. pylori infection, with smokers demonstrating a higher infection rate compared to non-smokers.Aims:This study aims to determine the most accurate and reliable diagnostic method for detecting H. pylori among smokers. Method:A comparative analysis was conducted between two rapid diagnostic tools: the Diaspot Rapid One Test and the Advanced Quality Rapid Anti-H. pylori Test. Both tests were applied to blood and stool samples collected from 100 male and female smokers at Al-Mustafa University College over a five-month period (September 2019–February 2020).Findings:Results revealed that 10% of the blood samples tested positive, whereas all stool samples returned negative results.Results:These findings suggest that stool testing may offer more accurate detection, as blood antibodies can persist even after the infection has resolved, potentially causing false positives. The study highlights the limitations of relying on a single diagnostic method, especially in smokers, and recommends the adoption of multimodal diagnostic approaches to enhance accuracy in high-risk populations.

Highlights:

1. Stool tests may be more accurate for current infections.
2. Blood antibodies can cause false positives.
3. Smokers are at higher risk for H. pylori infection.

Keywords: Helicobacter Pylori, Smokers, Rapid Diagnostic Test, Stool Testing, Blood Antibody

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Introduction

Helicobacter pylori is a microaerophilic, gram-negative bacterium that colonizes the gastrointestinal tracts of humans. It is one of the most prevalent bacterial infections

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worldwide, affecting approximately 50% of the global population. Among those infected, about 10% develop peptic ulcers, and 1% progress to gastric cancer, making H. pylori a significant public health concern [1]. The bacterium's unique morphology, characterized by its S-shape and polar, sheathed flagella, enables it to navigate the viscous mucus layer of the stomach. Additionally, surface urease production neutralizes gastric acid, allowing H. pylori to survive in the highly acidic environment of the gastric mucosa and contribute to disease pathogenesis [2]. The genus Helicobacter belongs to The class Epsilonproteobacteria, order Campylobacterales, and family Helicobacteraceae also include other genera such as Wolinella, Flexispira, Sulfurimonas, Thiomicrospira, and Thiovulum [3]. Recent genomic studies have revealed significant genetic diversity among H. pylori strains, which may influence their virulence and adaptation to different host environments [4]. This genetic variability underscores the complexity of H. pylori infections and their clinical outcomes, highlighting the need for ongoing research into its epidemiology and pathogenicity [5]. Lifestyle factors, particularly smoking, play a critical role in modulating the risk and severity of H. pylori-associated diseases. Cigarette smoking is a well-established risk factor for peptic ulcer disease and dyspeptic symptoms, partly due to its immunosuppressive effects, which may predispose individuals to H. pylori infection [6]. Moreover, smoking has been linked to increased antibiotic resistance in H. pylori, complicating treatment efforts [7]. Advances in diagnostic methods have improved the detection of H. pylori, with polymerase chain reaction (PCR) emerging as a highly sensitive and specific tool for identifying the bacterium in various clinical samples, including gastric biopsies, stool, and saliva [8]. However, the lack of a universally accepted gold standard for diagnosis remains a challenge, highlighting the need for further research to optimize diagnostic accuracy and patient outcomes [9].

Related Works

The detection of Helicobacter pylori (H. pylori) infection, particularly among smokers, is an important area of research due to its strong association with gastrointestinal diseases. Smoking has been shown to significantly increase the failure rate of H. pylori eradication therapies, as it alters gastric mucosal immunity, impacting the success of treatments and the accuracy of diagnostic tests [10]. Studies have also found a strong association between smoking and increased susceptibility to H. pylori infection, with smokers exhibiting a higher prevalence of infection compared to non-

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smokers [11]. Diagnostic methods like serum H. pylori IgG antibody and stool antigen tests (SAT) have been evaluated for their efficacy, with SAT demonstrating superior specificity and sensitivity, particularly in populations with high infection prevalence [12]. Comparative analyses of various diagnostic methods, including rapid urease tests, histology, culture, and serology, indicate that stool antigen tests and serology are reliable, less invasive options, though their performance can be influenced by factors such as antibiotic use and gastric pH levels [13]. Rapid diagnostic tools like the Advanced Quality Rapid Anti-H. pylori Test, a colloidal gold-enhanced immunochromatographic assay, provides quick results but may have limitations depending on the patient's immune status and prior exposure to the bacterium [14]. Smoking further complicates H. pylori diagnostics by increasing the prevalence of gastric conditions like intestinal metaplasia and erosive gastritis, underscoring the need for careful diagnostic and therapeutic approaches in smokers [15]. Commercially available rapid test kits, such as the Diaspora High Quality One Step H. pylori Test, offer convenience but require complementary clinical evaluation to ensure accuracy [16]. A study by Saadi and Saeed investigated the relationship between age and H. pylori infection using ELISA IgG, IgM, and IgA tests. The study found that the likelihood of H. pylori infection increased with age, while smoking and residence had no significant impact on infection rates. These findings highlight the importance of age as a demographic factor in understanding H. pylori prevalence and suggest that smoking may not be a critical variable in this context [18]. Iannone et al. presented a new fecal test for non-invasive H. pylori identification, highlighting its potential for evaluating antibiotic-resistant bacteria and its diagnostic accuracy. High agreement between the research and the gold-standard 12C-urea breath test was shown. However, there were several drawbacks, such as the use of only one non-invasive test and the restriction of confirmation testing for elderly people. This work emphasizes the necessity of comprehensive testing protocols, especially in younger populations, and adds to the continuing discussion on the validity of non-invasive diagnostic techniques [18].Gong et al. conducted a meta-analysis in 2021 to assess the diagnostic precision of PCR-based assays for identifying clarithromycin resistance in Helicobacter pylori (H. pylori) infections. Eleven studies were included in the analysis, which demonstrated the therapeutic use of these tests in the treatment of illnesses linked to H. pylori. The results highlight the potential of PCR-based stool testing as a

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trustworthy method for detecting antibiotic resistance, which is essential for directing successful therapeutic approaches [19]. These results highlight the value of multimodal diagnostic approaches in addressing the problems caused by H. pylori infection and smoking.

Method

A. Materials

This study utilized various materials to evaluate the diagnostic efficacy of the Diaspot Rapid One Test and the Advanced Quality Test in detecting Helicobacter pylori (H. pylori) infection. The materials were sourced from different manufacturers to ensure the availability of reliable diagnostic kits and supporting tools required for sample collection and analysis. The study employed rapid diagnostic kits for blood and stool samples, along with standard laboratory tools for specimen collection and processing [20]. Table 1 provides a detailed list of the materials used, including their origin and manufacturers. These materials were selected based on their widespread use in clinical settings and their ability to provide accurate and reproducible results. The use of internationally sourced kits and tools ensures the study's findings are applicable across diverse healthcare environments [21].

Table 1. Details of the materials

No.	Materials	Company	Origin
1	H.Pylori kit (Diaspot Rapid One Test)	IVD	China
2	H.Pylori kit (Rapid Card Test)	IVD	Jordan
3	Syringe	Sanity pharma	China
4	Plane Tube	AFCO	Jordan
5	Stool Cup	AFCO	Jordan
6	Wood Sticks	-	Local market

B. Methods of Collecting Samples

Accurate sample collection is crucial for the reliable detection of Helicobacter pylori (H. pylori) infection. This section outlines standardized procedures for obtaining blood

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and stool samples, adhering to current best practices to ensure specimen integrity and test accuracy.

1. H. pylori Blood Sample Test Procedure

Standardised blood sample collection is essential to the accuracy of serological test findings. Medical personnel who have received specialised training in venipuncture and sample management should be the only ones taking blood samples. These rules are intended to guarantee test value reliability and repeatability. The guidelines are suggestions and rules that each individual must adhere to in their job, not regulatory standards [22]. The stages involved in the H. pylori blood sample test are as follows:

a. Preparation: Allow the test device to equilibrate to room temperature (20-30°C) for 30 minutes. Do not open the inner packaging until ready, as it must be used within one hour after opening (humidity: 20-90%, temperature: 10-50°C).
b. Sample Application: Serum/Plasma: Add 1 drop (25 µl) of serum or plasma vertically into the sample pad or hole, followed by 2 drops (80-100 µl) of sample buffer.
c. Whole Blood: Add 2 drops (50 µl) of whole blood vertically into the sample pad or hole, followed by 2 drops (80-100 µl) of sample buffer.
d. Result Interpretation: Observe the results within 15-20 minutes. Results are invalid after 20 minutes.

2. H. pylori Stool Sample Test Procedure

In order to take a stool sample, the patient must be prepared. Faeces can be deposited straight into the designated container or passed into a clean, disposable plastic container at home before being transferred to a screw-top stool collecting container. The latter lessens the possibility of contamination. In order to prevent diluted samples and to precisely determine the antigen concentration, we choose this direct procedure. A sterile screw-top plastic container with a suitable label—possibly with a preservative—is required. For test integrity to be guaranteed, patients must be told to send the sample to the lab as soon as possible [23].

To identify H. pylori antigen, the stool sample test is carried out as follows:

1. Preparation: Bring the test kit, specimens, and buffer to room temperature (15-30°C). Remove the test from its sealed pouch and place it on a clean, level surface. Label the test with patient or control identification.

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2. Sample Application: Break the tip of the dilution tube and dispense 3 drops of the solution into the specimen well (S) of the test device. Avoid air bubbles and ensure no solution is added to the result area.
3. Result Interpretation: Wait for colored bands to appear. Read the results within 15 minutes. Do not interpret results after 20 minutes. If particles prevent migration, centrifuge the sample, collect 100 µl of supernatant, and repeat the test.

Result and Discussion

The study was conducted on 100 random samples from smokers at Al-Mustafa University College, focusing on detecting Helicobacter pylori infection using blood and stool samples.

From the 100 samples:

Blood samples: A positivity rate of 10% was observed, calculated as $\frac{10}{100}\ x\ 100$ = 10%

Stool samples: A positivity rate of 0% was recorded, calculated as $\frac{0}{100} x100$ = 10%

Table 2. Demographics and H. pylori Test Results by Age and Gender

No.	Age	Sex	Blood	Stool
1	35	male	+	-
2	37	male	-	-
3	51	male	-	-
4	29	female	+	-
5	24	male	-	-
6	21	male	-	-
7	23	male	+	-
8	23	male	+	-
9	23	male	+	-
10	33	female	-	-

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11	19	male	+	-
12	31	male	-	-
13	21	male	+	-
14	26	male	-	-
15	21	male	-	-
16	70	male	-	-
17	68	female	-	-
18	36	male	+	-
19	22	male	-	-
20	28	female	+	-
21	26	male	-	-
22	26	male	-	-
23	44	female	-	-
24	19	male	-	-
25	56	male	+	-

Table 2 and Fig.1 illustrate the distribution of H. pylori test results based on age and gender. The X-axis categorizes participants by gender (male and female) and their test results (positive "+" or negative "-"), while the Y-axis represents their ages. The blue bars depict the age of participants, and the orange bars show the number of individuals in each group. The chart reveals that males constitute most of the sample, with positive and negative test results distributed across various age groups. Positive cases are observed in both genders, with a noticeable concentration in younger and middle-aged individuals, highlighting potential age-related patterns in H. pylori prevalence.

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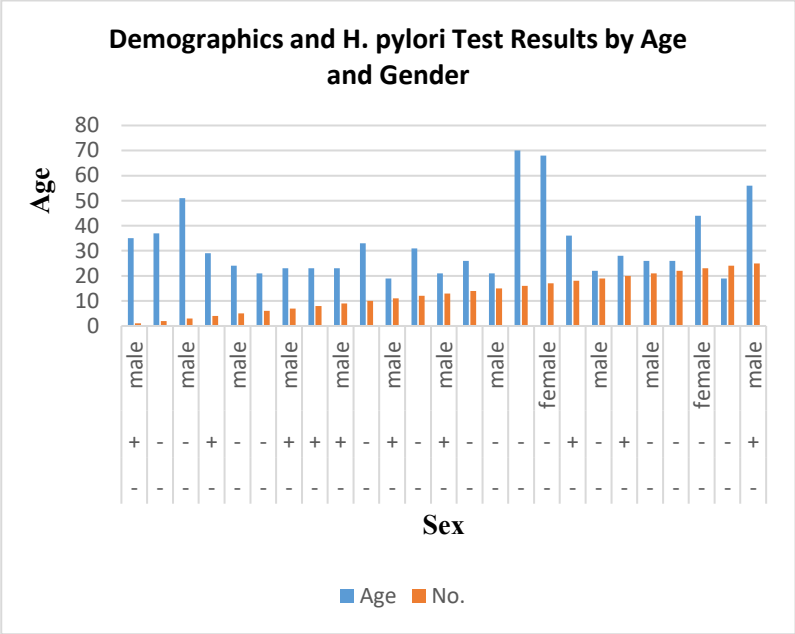

Fig 1. Demographics and H. pylori Test Results by Age and Gender

Two diagnostic tests for H. pylori infection are shown in Fig. 2, with an emphasis on their positive findings. As test 1 indicates, the faecal antigen test (HP-Ag) confirms the presence of H. pylori antigens in the faecal sample by displaying two bands: one at the test line (T) and one at the control line (C). Similarly, test 2 for serology reveals two different bands, which suggests that the blood contains IgG antibodies specific to H. pylori. These findings indicate that an H. pylori infection has been diagnosed and demonstrate that both tests are capable of detecting biomarkers linked to H. pylori.

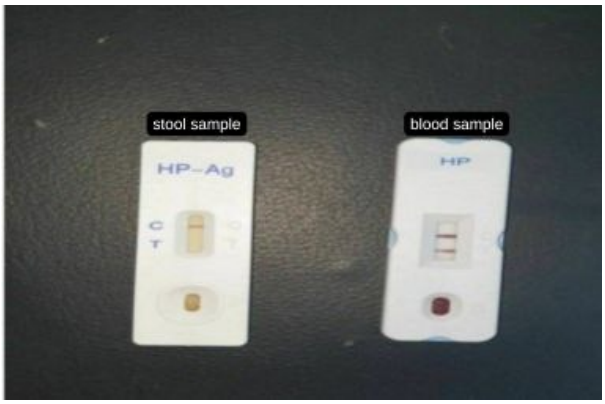

Fig 2. Positive and negative results of tests 1 is the negative result of feces and 2 is the positive result of blood.

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The serological and faecal antigen test findings are negative, as seen in Fig. 4. When there is just one band visible at the control line (C) of the faecal antigen test (HP-Ag), there are no identifiable H. pylori antigens in the faecal sample. Similarly, there is no indication of an immunological response to H. pylori in the blood, as indicated by the solitary band at the control line (C) of the serology test for H. pylori IgG antibodies. These results show that there is no infection, as both tests consistently yield negative results.The findings in the literature on the distinctions between stool antigen testing and serology testing for H. pylori diagnosis are consistent with the results displayed in Fig.2 and 3.

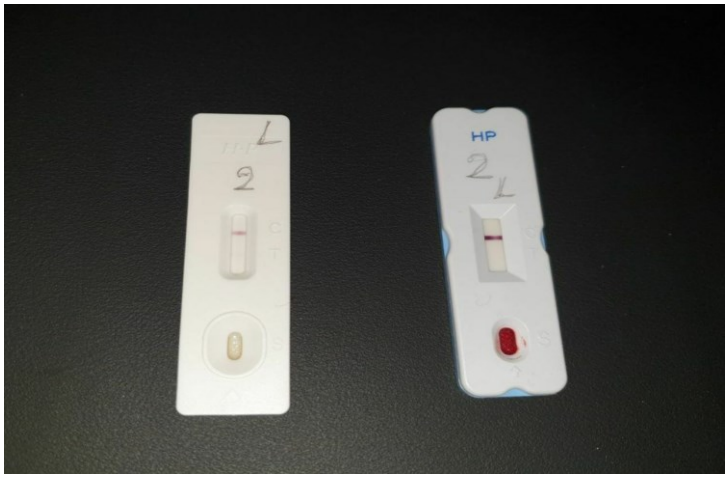

Fig 3. Positive and negative results of tests 1 is the negative result of feces and 2 is the negative result of blood

Table 3. Comparison of Performance Parameters Between Stool Antigen and Serology Tests

Test Type	Positivity Rate (%)	Sensitivity (%)	Specificity (%)	Accuracy (%)	AUC (%)
Stool Antigen Test	28.2	100	98.7	99	99.3
Serology Test	48.3	59.8	57.9	60	61.4

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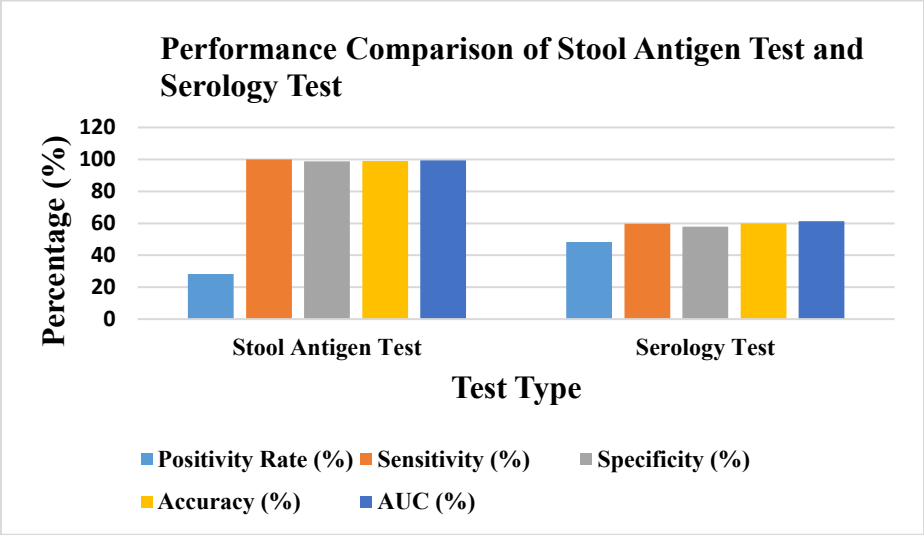

Fig 4. Performance Comparison of Stool Antigen Test and Serology Test

The performance metrics of the stool antigen test and the serology test in identifying H. pylori are contrasted in Fig.4 and the accompanying Table 2. The stool antigen test had a lower positive rate (28.2%) than the serology test (48.3%). However, as IgG antibodies can remain after an illness has cleared up, this discrepancy is probably caused by the serology test's capacity to identify previous infections. For both tests, there were no appreciable variations in positive rates by gender, age group, or region. However, in the serology test, those over 60 showed considerably higher positive rates ($P<0.05$) than those between 18 and 39 and 40 and 59, indicating an age-related tendency that may be due to past infections or chronic exposure.In every important metric, such as sensitivity (100% vs. 59.8%), specificity (98.7% vs. 57.9%), and accuracy (99% vs. 60%), the stool antigen test showed improved diagnostic performance. The stool antigen test demonstrated the capacity to reliably detect active H. pylori infections by achieving a significantly greater area under the Receiver Operating Characteristic (ROC) curve (99.3% vs. 61.4%) than the serology test. These findings highlight the clinical use and dependability of the stool antigen test in detecting active infections, but the serology test would be more appropriate for assessing previous exposure.Overall, the stool antigen test's excellent sensitivity and specificity guarantee precise identification of genuine positive and true negative cases, thus its lower positivity rate does not impair its diagnostic effectiveness. The stool antigen test is the more dependable and therapeutically useful method for identifying active H. pylori infections, since the serology

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test's lower sensitivity and specificity restrict its capacity to distinguish between active and previous infections.

Conclusions

This study highlights the importance of accurately diagnosing H. pylori, a dangerous infection in humans that, if left untreated, can lead to severe complications, including stomach cancer. The findings confirm that the stool antigen test is more reliable and accurate in diagnosing active H. pylori infections compared to the serology test, which may detect antibodies long after the infection has resolved. Smoking is identified as a significant risk factor for H. pylori infections due to its negative impact on immunity, making smokers more susceptible. Furthermore, maintaining proper hygiene in food preparation is critical to reducing the risk of transmission.

Based on these findings, it is recommended that individuals experiencing stomach discomfort, especially smokers or those suspected of H. pylori infection, quit smoking and seek medical attention promptly. Stool-based testing should be prioritized for diagnosing active H. pylori infections due to its superior specificity and accuracy. Future research should aim to enhance the availability and affordability of stool antigen tests, particularly in resource-limited settings. Additionally, exploring the integration of molecular diagnostic techniques, such as PCR, and developing innovative, point-of-care tools can further improve diagnostic accuracy. Emphasizing hygiene practices and raising awareness about the risks of H. pylori are also vital steps to minimize infections and their complications.

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