

## ORIGINAL ARTICLE

**A comparative study of stool antigen Immunocard STAT HpSA test with biopsy in diagnosis of H Pylori Infection**Munish Rastogi<sup>1</sup>, Dolly Rastogi<sup>2</sup>, Shraddha Singh<sup>3</sup>, Sunita Tewari<sup>4</sup>, Asha Agarwal<sup>5</sup>, Tanu Midha<sup>6</sup>

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**Abstract**

The present study was conducted on 78 cases in the Department of Medicine at G.S.V.M Medical College, Kanpur who reported with various gastrointestinal symptoms such as dyspepsia, heartburns, nausea, vomiting and loss of appetite. They all were advised for biopsy by the physician. Patients treated with antibiotics, bismuth or proton pump inhibitors within 4 weeks preceding the study were excluded. Invasive tests using mucosal biopsies including histology and rapid urease test (RUT) were used to establish the gold standard in order to evaluate the accuracy of Immunocard STAT HpSA. Sensitivity, Specificity, Positive Predictive Value and Negative Predictive Value of Immunocard STAT HpSA as compared to gold standard were 95.5%, 81.8%, 96.9% and 75.0% respectively. It is thus concluded that the Immunocard STAT HpSA test has a diagnostic value comparable to the gold standard in detecting H Pylori. The sensitivity and specificity of the test is fair enough to be used as a test for screening purpose and also for diagnosis and treatment of H. Pylori infection in clinical practice

**Key Words**

Immunocard STAT HpSA; H. Pylori; Sensitivity; Specificity; Positive Predictive Value; Negative Predictive Value

**Introduction**

Helicobacter Pylori infection is a major cause of chronic gastritis and peptic ulcer, and is associated with gastric cancer (1,2,3). It is estimated that about 50% of the World's population has H. Pylori colonization in the gastric mucosa (4). There are several methods of diagnosing H. Pylori infection including invasive procedures using mucosal biopsies taken during endoscopy (mainly histology and rapid urease test) and non-invasive procedures (mainly 13C urea breath tests and serological tests). But invasive procedures like biopsy, endoscopy and urea

breath tests require expensive equipment or are harmful to patients. Also the serological tests lack sensitivity and specificity as H. Pylori antibody titres fall very slowly even after successful eradication (5, 6).

**Aims & Objectives**

To evaluate the clinical value of a new test, Immunocard STAT HpSA for the diagnosis of H. Pylori infection.

**Material and Methods**

A total of 78 patients participated in the study. All these patients reported with various gastrointestinal

symptoms such as dyspepsia, heartburns, nausea, vomiting and loss of appetite. They were all advised for biopsy by the physician. Patients treated with antibiotics, bismuth or proton pump inhibitors within 4 weeks preceding the study and those with bleeding peptic ulcer or past gastric surgery were excluded. Invasive tests using mucosal biopsies including histology and rapid urease test (RUT) were used to establish the gold standard in order to evaluate the accuracy of Immunocard STAT HpSA.

During upper GI endoscopy, three gastric biopsies were done from the antrum of the stomach, one for (RUT) rapid urease test and remaining two for staining. The gold standard for presence of H. Pylori infection was defined as both RUT and staining positive. The absence of H. Pylori infection required these tests to be negative.

**Immunocard STAT HpSA** – On the same day of endoscopy, 10 ml of the patient's stool was collected into a clean air-tight container, with no preservatives. The stool was shifted immediately to the laboratory. The stool assay was performed using the Immunocard STAT HpSA (Standard Diagnostic Inc). Stool samples were collected in air tight containers. The stool assay was performed using immunocard STAT HpSA. The positive and negative results were judged as recommended by the manufacturers. This test was being used for screening of the subjects for H. Pylori Infection. The test device and the sample were brought to room temperature prior to testing. The test device was laid on a flat dry surface and about three drops of the prepared sample were poured into the sample well. Interpretation was done after fifteen minutes. Two colour bands, one at test band and another at control band indicated a positive result. Negative test results showed only control band. The endoscopy based tests and HpSA test were carried out by different people with double blind procedures. **Statistical Analysis** – Specificity, sensitivity, PPV and NPV of the HpSA test in comparison to gold standard were calculated using SPSS 20.0.

## Results

A total of 78 patients were tested by Immunocard STAT HpSA and the endoscopy based tests. Among these, H. Pylori infection was present in 67 patients as determined by gold standard. HpSA test was positive in 64 and negative in 3 patients. Compared with gold standard the HpSA gave false positive in 2

and false negative in 3 patients. Sensitivity, Specificity, Positive Predictive Value and Negative Predictive Value of Immunocard STAT HpSA were then calculated ([Table 1](#)).

Sensitivity =  $64/67 \times 100 = 95.5\%$

Specificity =  $9/11 \times 10 = 81.8\%$

Positive Predictive value =  $64/66 \times 100 = 96.9\%$

Negative Predictive value =  $9/12 \times 100 = 75.0\%$

## Discussion

Various invasive tests are available to diagnose H. Pylori infection. Though these tests are highly sensitive and specific but have certain limitations. Mucosal biopsies taken during endoscopy might lead to cross – infection and sometimes patients refuse to undergo endoscopy especially the pediatric patients. The urea Breath Tests have proven to have high sensitivity and specificity and are considered to be the optimal test for monitoring H. Pylori eradication therapy. However, 13C-UBT need special equipment and is expensive and 14C-UBT requires a radioactive isotope; and cannot be used for children and pregnant women. So, UBTs are not widely available. Due to these reasons, HpSA STAT test is better as it is easy, cheaper and accurate. Gastric epithelial cells renew once in one to three day which are excreted in feces with H. Pylori which can be detected by polyclonal capture anti H. Pylori antibodies, (7). The HpSA test has been widely evaluated around the World with a mean sensitivity and specificity of 90 – 98% respectively, (8,9). The HpSA test is a cheap and useful method for the diagnosis of H. Pylori infection before and after eradication therapy (10). It is an accurate test in all paediatric age groups also, (11). Although HpSA test seems to be less accurate than the urea breath test (UBT), both UBT and stool antigen tests are reliable non-invasive tests for monitoring the efficacy of H. Pylori eradication therapy (7).

## Conclusion

In the present study, we conclude that the Immunocard STAT HpSA test has a diagnostic value comparable to the gold standard in detecting H. Pylori. The sensitivity and specificity of the test is fair enough to be used as a test for screening purpose and also for diagnosis and treatment of H. Pylori infection in clinical practice. Also it is easy and convenient to perform and can be used especially for children, pregnant women, old people and others who are not suitable for endoscopy.

**Recommendation**

Immunocard STAT HpSA is a very sensitive and fairly specific tool to identify cases of H. Pylori in the general population. It is non-invasive and easy to perform, therefore it is recommended as the ideal investigation for screening of cases of H. Pylori.

**Limitation of the study**

The limitations of the study are that the sample size is small and that it is a hospital based study. Further community based studies can be done to confirm the findings of the study.

**Relevance of the study**

There is a high prevalence of H. Pylori infection in the general population. Most of these cases are undiagnosed and use over the counter antacids for dyspepsia. A simple and convenient test like Immunocard STAT HpSA will be very useful in diagnosis and correct management of these cases. Earlier the diagnosis of H. Pylori infection was possible only on the basis of biopsy and histopathology, but with the evidence that Immunocard HpSA STAT test is very sensitive and specific as compared to biopsy and histopathology, this test can be recommended as the screening tool for diagnosis of H. Pylori infection.

**Authors Contribution**

MR-concept and design of the study, data collection and analysis, interpretation of findings, preparation of manuscript, DR-Data collection, interpretation of findings, preparation of manuscript, SS-concept and design of the study, data collection and analysis, interpretation of findings, preparation of manuscript, ST-concept and design of the study, interpretation of findings, preparation of manuscript, AA-Data analysis, interpretation of findings, preparation of manuscript, TM-Data analysis, interpretation of findings, preparation of manuscript.

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**TABLE 1 PERFORMANCE OF THE IMMUNOCARD STAT HPSA TEST IN THE DETECTION OF H. PYLORI INFECTION, ACCORDING TO THE BIOPSY BASED GOLD STANDARD.**

| Immunocard STAT HpSA | Gold standard |          |       |
|----------------------|---------------|----------|-------|
|                      | Positive      | Negative | Total |
| Positive             | 64            | 2        | 66    |
| Negative             | 3             | 9        | 12    |
| Total                | 67            | 11       | 78    |