Rapid Strip HpSA®

REF 750620 | Σ 20 tests | IVD For in vitro diagnostic use only

Meridian
Bioscience Europe

ENGLISH

Rapid Strip HpSA

Catalog # 750620 – 20 tests

A Rapid Immunoassay for the Detection of *Helicobacter pylori* Antigens in Stool Specimens

INTENDED USE

The Rapid Strip HpSA immunoassay is an *in vitro* qualitative procedure for the detection of *Helicobacter pylori* antigens in human stool. The stool antigen detection is intended to aid in the diagnosis of *H. pylori* infection, and to confirm the eradication after treatment. Accepted medical practice recommends that testing by any current method, to confirm eradication, be done at least four weeks following completion of therapy.

EXPLANATION

The importance of *Helicobacter pylori* in gastrointestinal diseases has increased greatly since Marshall and Warren described the presence of Campylobacter-like organisms in the antral mucosa of patients with histological evidence of antrum gastritis and peptic ulcers, especially duodenal ulcers (1,2). The strong correlation between the presence of *H. pylori* and histologically confirmed gastritis, peptic ulcer disease and gastric carcinoma, as well as disease resolution after *H. pylori* eradication, indicates a causative relationship (3,4,5).

The diagnostic strategies for the determination of *H. pylori* have been developed along two lines: 1) direct detection of the organism, and 2) detection of antibodies made against *H. pylori*.

Direct detection by invasive methods requires that a biopsy be taken from the upper gastrointestinal tract. The presence of *H. pylori* is then confirmed by direct microscopic examination, rapid urease testing or culturing of the organism from the biopsy material. This strategy has the advantage of being able to detect active infections while being highly specific with a very high positive predictive value. The difficulties associated with this approach are risk and discomfort to the patient. In addition, *H. pylori* tends to colonize in patches and may be missed totally by the biopsy. Culturing of *H. pylori* from biopsy material tends to be difficult and time-consuming. These technical difficulties may lead to false negative results (6,7,8).

The urea breath test (using ^{14}C or ^{13}C - urea) is a noninvasive method that detects *H. pylori* by exploiting its highly active urease (9). Though highly sensitive and specific, the test has limitations. It is expensive, time-consuming, and requires ingestion of isotopically labeled urea as well as specialized instrumentation for the detection of ^{14}C or ^{13}C.

The most common noninvasive approach to the detection of *H. pylori* is the serological identification of specific antibodies in infected patients. Though an indirect approach, the correlation between histological gastritis, the presence of *H. pylori* and seropositivity is extremely strong. The disadvantages of these tests are that the antibodies persist for a long time after a successful eradication, giving false positive results (10,11,12).

Meridian Bioscience, Inc. introduced the concept of detecting *H. pylori* antigens in stool specimens, with a microtiter based immunoassay, in 1997. Premier Platinum HpSA, after extensive evaluation, was accepted as an accurate tool for non-invasive Helicobacter pylori infection diagnosis (13,14,15).

Recent official European Guidelines (16) recommend the use of either Stool Antigen or Urea Breath test for diagnosis and confirmation of eradication four weeks after the end of the treatment.

Rapid Strip HpSA is a rapid 5 minutes immunoassay, based on a lateral flow chromatography technique that detects *H. pylori* antigens present in human stool.

BIOLOGICAL PRINCIPLES

The **Rapid Strip HpSA** test utilizes a monoclonal anti-*H. pylori* antibody. The strip is introduced in a tube containing diluted patient samples and the appearance of a pink-red line in the reading area indicates a positive result after 5 minutes of incubation at room temperature.

MATERIALS PROVIDED

1. HpSA strips (20) – individually foil pouched, containing immobilized anti-*H.pylori* monoclonal antibody (test zone).
2. Sample Diluent bottle (1) – Each bottle contains 25 ml of Sample Diluent.

MATERIALS NOT PROVIDED:

1. Disposable latex gloves, that should be used during the handling of the fecal samples as they are considered potential hazard material.
2. Swabs/applicators for stool sample collection.
3. Vortex for suspension of the stool specimen in the sample diluent.
4. Test tubes for sample dilution.
5. Transfer pipets.
6. Timer.

PRECAUTIONS

1. All reagents are for *in vitro* use only.
2. Patient specimens may contain infectious agents and should be handled and disposed of as potential biohazards.
3. Do not interchange reagents from different kit lot numbers.
4. Allow kit components and specimens to reach the room temperature before use, as cold reagents and/or specimens may decrease assay performances. 20-30 minutes are recommended.
5. Do not use kit components beyond labeled expiration date.
6. Stool must be mixed thoroughly (regardless of consistency) to insure a representative sample prior to sampling.

SHELF LIFE AND STORAGE

The expiration date is indicated on the kit label. Store the kit at 2°-8°C. Do not freeze.

SPECIMEN HANDLING

The specimen should be received in an airtight transport container and stored at 2°-8°C until tested. The specimen should be tested as soon as possible, but may be held up to 72 hours at 2°-8°C prior to testing. If testing cannot be performed within this time frame, specimens should be frozen immediately upon receipt and stored frozen (-20°C to -80°C) until tested. Specimens may be frozen and thawed twice.

NOTE: Stool in transport media, swabs, or preservatives are inappropriate for testing.

SPECIMEN PREPARATION

Mix stool as thoroughly as possible prior to sampling.

Watery, diarrheal specimens are inappropriate for testing.

PROCEDURE

1. Transfer 1.0 ml of sample diluent in a test tube or vial.
2. Add a sample portion of approximately 5-6 mm size, with a swab, a wooden applicator or a bacteriology loop, and shake gently in order to suspend it into the diluent.

3. Vortex for 15 seconds.
4. Wait at least 3 minutes until the solid particles settle and transfer 500 microliters of supernatant to another test tube, with a pipette.
5. Dip the reaction strip in the second test tube with the arrow pointing to the bottom. IMPORTANT: the liquid must not reach the blue area above the arrowheads. If needed, use a larger tube or reduce the amount of sample.
6. Read the result after exactly 5 minutes in the white area.

Note: the strip can also be introduced into the first tube or vial, provided it is large enough to avoid the liquid to reach the blue area above the arrowheads. However, in rare cases, when using a too concentrated diluted specimen, the absorption might be difficult.
Alternatively, the strip can be dipped for 10 seconds in the first tube, avoiding to exceed the arrowheads, and then transferred to the bench top for the incubation.

INTERPRETATION OF RESULTS

Negative test result: only one BLUE coloured band (Control Line) appears across the white central area of the reaction strip. *H.pylori* antigens are absent or below the level of detection.
Positive test result: In addition to the BLUE band (Control Line), a distinguishable PINK-RED band (Test Line) also appears across the white central zone of the reaction strip. The intensity of the band will be variable depending on the antigen concentration in the specimen. Any pink-red line, even very weak, must be considered as a positive result. Any line or colour appearing after 5 minutes has no diagnostic value. A positive test line indicates that there are detectable *H.pylori* antigens in the specimen.
Invalid test result: the BLUE band (Control Line) is absent, with or without a visually detectable PINK-RED band (Test Line).

QUALITY CONTROL

If no Control Line band appears across the white central zone of the reaction strip the test is invalid, since improper test procedure was carried out or deterioration of the reagents has occurred.

LIMITATIONS OF THE PROCEDURE

1. The test is qualitative and no quantitative interpretation should be made with respect to the intensity of the positive line, when reporting the result.
2. Test results should be used in conjunction with information available from the patient clinical evaluation and other diagnostic procedures.
3. Antimicrobials, proton pump inhibitors and bismuth preparations are known to suppress H. pylori, and ingestion of these prior to H. pylori testing (culture, histology, rapid urease, UBT, antigen) may give a false negative result. If a negative result is obtained for a patient ingesting these compounds within two weeks prior to performing the Rapid Strip HpSA test, it may be a false negative result and the test should be repeated on a new specimen obtained two weeks after discontinuing treatment. A positive result for a patient ingesting these compounds, within two weeks prior to performing the Rapid Strip HpSA test, should be considered accurate.
4. Performance characteristics have not been established for watery, diarrheal stools.

EXPECTED VALUES

Studies on the epidemiology of *H. pylori* have shown that this organism is present worldwide (17,18,19). Gastritis caused by *H. pylori* has been shown to correlate with age, ethnic background, family size and socioeconomic class (20,21). The prevalence of *H. pylori* infection in a given population can vary from 20% to 90%.In patients diagnosed with duodenal ulcers, however, it has

been shown in every age group to be approximately 80% (17). Currently recommended eradication treatments have a efficacy rate between 75% and 90%. Therefore, after a therapy, up to 25% of patients can still be infected.
The Rapid Strip HpSA test detects the presence of *H. pylori* antigens in human stool. Expected values for a given population should be determined for each laboratory. The rate of positivity may vary depending on geographic location, method of specimen collection, handling and transportation, test employed and general health environment of patient population under study.

PERFORMANCE CHARACTERISTICS
The Rapid Strip HpSA test was evaluated in a reference gastroenterology hospital department. 104 consecutive dyspeptic patients, not using acid suppressant therapy or antibiotics, referred for endoscopy were enrolled. All patients provided a stool specimen.
Biopsy specimens were taken for histology, rapid urease test and culture. Patients were defined as H.pylori infected if histology and urease tests were positive, or if culture was positive. 51/104 patients were found H.pylori positive.The results are summarized in the following table.

Rapid Strip HpSA	DIAGNOSIS	
	Infected	Not infected
Positive	49	5
Negative	2	48

From the table, the following performance characteristics, with 95% confidence interval, were calculated:

	%	95% CI
Sensitivity	96.1	86.5-99.5
Specificity	90.6	79.3-96.9
Positive Predictive Value	90.7	79.7-96.9
Negative Predictive Value	96.0	86.3-99.5
Correlation	93.3	86.6-97.2

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ImmunoCard H.pylori IgG Helicobacter IgG antibody detection rapid enzyme immunoassay	30 tests	710030

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