SPECTRUM

The Creative Approach to Bioscience

H. pylori Ag Rapid Test Cassette (Fecal Specimen)

REF: 1184 001 30 test

INTENDED USE

The Spectrum H. pylori Ag Test Device is a lateral flow chromatographic immunoassay for the qualitative detection of H. pylori antigen in human fecal specimen. It is intended to be used by professionals as a screening test and as an aid in the diagnosis of infection with H. pylori. Any reactive specimen with the Spectrum H. pylori Ag Test Device must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY

Helicobacter pylori is associated with a variety of gastrointestinal diseases included non-ulcer dyspepsia, duodenal and gastric ulcer and active, chronic gastritis1,2. The prevalence of H. pylori infection could exceed 90% in patients with signs and symptoms of gastrointestinal diseases. Recent studies indicate an association of H. pylori infection with stomach cancer.

H. pylori can be transmitted by means of oral–fecal matter through the ingestion of waste tainted food or water. Antibiotics in combination with bismuth compounds showed to be effective in treating active H. pylori infection.

H. pylori infection is currently detected by invasive testing methods (ie histology, culture) based on endoscopy and biopsy, or non-invasive testing methods, such as urea breath test (UBT), serologic antibody test and stool antigen test. UBT requires one month long preparation and consume radioactive material. Serologic antibody tests do not distinguish between currently active infection with a past exposure or an infection that has been cured. The stool antigen test detects antigen presence in the feces that indicates active H. pylori infection. It can be also used to monitor the effectiveness of treatment and the recurrence of the infection.

The Spectrum H. pylori Ag Test Device uses a colloid gold conjugated monoclonal anti- H. pylori antibody and another monoclonal anti-H. pylori antibody to specifically detect H. pylori antigen present in the infected patient fecal specimen. The test is user friendly, accurate, and the result is available instantly.

TEST PRINCIPLE

The H.pylori Antigen Rapid Test Cassette (Fecal specimen) is a qualitative, lateral flow immunoassay for the detection of H.pylori antigens in human feces specimens. In this test, the membrane is pre-coated with anti-H.pylori antibodies on the test line region of the test. During testing, the specimen reacts with the particle coated with anti-H.pylori antibodies. The mixture migrates upward on the membrane by capillary action to react with anti-H.pylori antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS AND MATERIALS PROVIDED

The test cassette contains monoclonal anti-H.pylori antibodies coated particles and monoclonal anti-H.pylori antibodies coated on the membrane.

1. Test Cassettes
2. Specimen collection tubes with extraction buffer
3. Package inserts.

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer
- Droppers
- Centrifuge

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Temperature Limitation
IVD	For in-vitro diagnostic use		Use by/Expiration Date
LOT	Batch Code/Lot number		CAUTION. Consult instructions for use
REF	Catalogue Number		Manufactured by
	Consult instructions for use		

WARNINGS AND PRECAUTIONS

For in Vitro Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use any kit components beyond their stated expiration date.
4. Do not use the components in any other type of test kit as a substitute for the components in this kit.
5. Bring all reagents to room temperature (15°C-30°C) before use.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
7. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Extraction buffer contains 0.1% NaN3. Avoid contact with skin or eyes. Do not ingest.
10. Dispose of all specimens and materials used to perform the test as biohazardous waste.
11. The testing results should be read within 15 minutes after a specimen is applied to the sample well of the device. Read result after 15 minutes may give erroneous results.
12. Do not perform the test in a room with strong air flow , ie. electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTION

All reagents are ready to use as supplied. Store unused test devices unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

SPECIMEN COLLECTION AND PREPARATION

1. The feces specimen must be collected in clean, dry, waterproof container containing no detergents, preservatives or transport media.
2. Bring the necessary reagents to room temperature before use.
3. If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

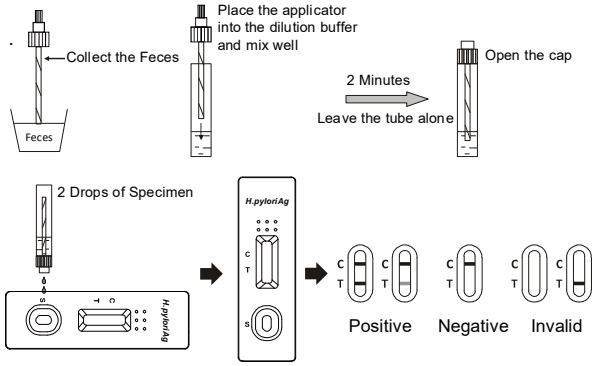
TEST PROCEDURE

Allow the test cassette, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

To collect fecal specimens:

1. Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8℃ if not tested within 6 hours. For long term storage, specimens should be kept below -20℃.
2. To process fecal specimens:
   - **For Solid Specimens**:
     Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.
   - **For Liquid Specimens:**
     Hold the dropper vertically, aspirate fecal specimens, and then transfer 2 drops (approximately 80 µL) into the specimen collection tube containing the extraction buffer.

3. Tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Leave the tube alone for 2minnutes.
4. Bring the pouch to room temperature before opening it. Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
5. Hold the specimen collection tube upright and open the cap onto the specimen collection tube. Invert the specimen collection tube and transfer 2 full drops of the extracted specimen (approximately 80 µL) to the specimen well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
6. Read results at 10 minutes after dispensing the specimen. Do not read results after 20 minutes.
   Note: If the specimen does not migrate (presence of particles), centrifuge the extracted specimens contained in the extraction buffer vial. Collect 80 µL of supernatant, dispense into the specimen well (S) of a new test cassette and start afresh following the instructions mentioned above.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:* Two distinct colored lines appear. One line should be in the control line region (C) and another line should be in the test line region (T).

***NOTE:** The intensity of the color in the test line region (T) may vary depending on the concentration of H.pylori antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No apparent colored line appears in the test line region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal Control: This test contains a built-in control feature, the C band. The C line develops after adding specimen extract. Otherwise, review the whole procedure and repeat test with a new device.

2. External Control: Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performance of the assay,

LIMITATIONS OF TEST

1. The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of H. pylori antigen in feces. Failure to follow the procedure, in particularly sampling procedure, may give inaccurate results.
2. The Spectrum H. pylori Ag Test Device is limited to the qualitative detection of H. pylori antigen in human fecal specimen. The intensity of the test band does not have linear correlation with antigen title in the specimen.
3. A negative result for an individual subject indicates absence of detectable H. pylori. Antigen. However, a negative test result does not preclude the possibility of infection with H. pylori.
4. A negative result can occur if the quantity of the H. pylori antigen present in the specimen is below the detection limits of the assay, or the antigen that are detected are not present in fecal sample is collected.
5. If the symptom persists, while the result from Spectrum H. pylori Ag Test Device is negative or non-reactive result, it is recommended to re-sample the patient few days late or test with an alternative test device.
6. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

Expected Values

The The H.pylori Antigen Test Cassette (Feces) has been compared with Endoscope based methods,demonstrating an overall accuracy of 99.1 %.

PERFORMANCE CHARACTERISTICS

Clinical Performance

328 fecal samples collected from subjects with symptomatic gastrointestinal disorders and non-gastrointestinal symptoms were tested with the Spectrum H. pylori Ag Test Device with the UBT as reference test. Comparison for all subjects is shown in the following table:

Spectrum H. pylori Ag Test Device			
UBT	Positive	Negative	Total
Positive	118	7	125
Negative	0	199	199
Total	118	206	324

Relative Sensitivity: 94.4% , Relative Specificity: 100.0%, Overall Agreement: 97.8%

Analytic Sensitivity:

The detection limit for the Spectrum H. pylori Ag Test Device -is 5 ng/ml of H. pylori lysate. The fecal specimen extraction contains H. pylori lysate equal to or greater than 5 ng/ml routinely test positive. Specimens containing H. pylori lysate less than 5 ng/ml may also produce a very faint positive line, especially with extended assay time beyond 15 minutes.

The following experiments were done to validate the sensitivity of the Spectrum H. pylori Ag Test Device -Card:

Normal fecal extraction were spiked with H. pylori lysate to concentrations of 0, 1.25, 2,5, 5, 10, 20 ng/ml. The specimens were run on the Spectrum H. pylori Ag Test Device -. Results are tabulated in table below.

H. pylori lysate ng/ml	0	1.25	2.5	5	10	20
Number of positive	0	0	12	20	20	20
Number of negative	20	20	8	0	0	0

n=20 relative sensitivity at 5 ng/ml = 20/20 x 100% = 100%

REFERENCES

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