SPECTRUM

The Creative Approach To Bioscience

H. pylori Ag Test Device
(Fecal Specimen)

REF: 1184 001 30 test

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		
	Consult instructions for use		Manufactured by

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.

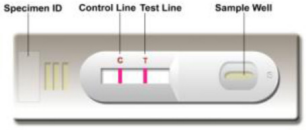
SUMMARY AND EXPLANATION OF THE TEST
Helicobacter pylori is associated with a variety of gastrointestinal diseases included non-ulcer dyspepsia, duodenal and gastric ulcer and active, chronic gastritis1,2. The prevalence of H. pylori infection could exceed 90% in patients with signs and symptoms of gastrointestinal diseases. Recent studies indicate an association of H. pylori infection with stomach cancer[3].

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 Spectrum H. pylori Ag Test Device is a sandwich lateral flow chromatographic immunoassay. The test strip consists of: 1) a burgundy colored conjugate pad containing monoclonal anti-H.pylori antibody conjugated with colloid gold (anti-H.P conjugates) and 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with another monoclonal anti-H.P antibody, and the C band is pre-coated with goat anti-mouse IgG antibody.



When an adequate volume of extracted fecal specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. H.P antigen if present in the specimen will bind to the anti-H.P conjugates. The immunocomplex is then captured on the membrane by the pre-coated antibody, forming a burgundy colored T band, indicating a H.P positive test result. Absence of this band suggests that the concentration of H.P in the specimen is below the detectable level, indicating a H.P negative result.

Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti-mouse IgG/mouse IgG-gold conjugate regardless of the color development on the T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED
1. Individually sealed foil pouches containing:
   a. One cassette test device.
   b. One desiccant.
2. Sample extraction tubes, each containing 2 mL of extraction buffer.
3. One package insert (instruction for use).

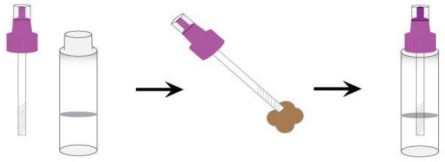
MATERIALS MAY BE REQUIRED AND AVAILABLE FOR PURCHASE
1. Positivia H. pylori Ag Test Device Assay Control Kit (Cat # C0192) contains one vial of positive control and one vial of negative control

MATERIALS REQUIRED BUT NOT PROVIDED
1. Clock or Timer
2. A container to hold fecal specimen

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 INSTRUCTIONS
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 HANDLING
Consider any materials of human origin as infectious and handle them using standard biosafety procedures.
1. Collect a random sample of feces in a clean, dry receptacle.
2. Unscrew the top of the collection tube and remove the applicator stick.
3. Randomly pierce the fecal specimen in at least five (5) different sites. ***Do not scoop fecal specimen as this will lead to invalid test result.***
4. Remove excess sample off the shaft and outer grooves. Be sure specimen remains on inside grooves. Specimen on the grooves is sufficient for testing. ***Excess amount of fecal can lead to invalid test result.***
5. Replace the stick in the tube and tighten securely.

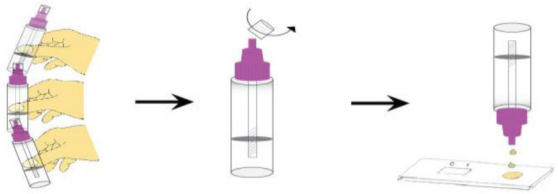


The specimen is now ready for testing, transportation or storage.

Note: Specimens collected may be stored 3 days at 2°C -8°C, or 1 year at <-20°C

TEST PROCEDURE

Step 1: Bring the specimen and test components to room temperature if refrigerated or frozen.
Step 2: When ready to test, open the pouch at the notch and remove the test strip. Place the test strip on a clean, flat surface.
Step 3: Shake the sample collection tube vigorously to ensure an effective liquid suspension.
Step 4: Hold the tube upright, twist off the tip. Dispense 2 drops of the solution into the sample pad (s) of the strip. Do not over load samples.



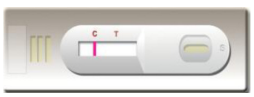
Step 5: Set up the timer.
Step 6: Results can be read in 15 minutes after adding the specimen. Positive results can be visible in as short as 1 minute.
Don't read results after 15 minutes. To avoid confusion, discard the test device after interpreting the result.

QUALITY CONTROL

1. **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, particularly under the following circumstances:
   a. New operator uses the kit, prior to performing testing of specimens.
   b. A new lot of test kit is used.
   c. A new shipment of kits is used.
   d. The temperature used during storage of the kit falls outside of 2-30^{O}C.
   e. The temperature of the test area falls outside of 15 -30^{O}C.
   f. To verify a higher than expected frequency of positive or negative results.
   g. To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

1. ***NEGATIVE RESULT:*** If only the C band is developed, the test indicates that no detectable H. pylori antigen is present in the specimen. The result is negative.



2. ***POSITIVE RESULT:*** If both C and T bands are developed, the test indicates for the presence of H. pylori antigen in the specimen. The result is positive.

Samples with positive results should be interpreted in conjunction with other testing procedure and clinical findings before a diagnostic decision is made.

3. ***INVALID:*** If no C band is developed, the assay is invalid regardless of color development on the T band as indicated below. Repeat the assay with a new device. ***If it is caused by excess amount of fecal specimen collected, re-sample and re-test.***

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%

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.

REFERENCES

1. Vans DJ, Evans DG, et at A sensitive and specific seriologic test for detection of campylobacter pylori infection. Gastroenerology. 1989, 96:1004
2. Lambert IR, Lin SK, and Aranda-Michel. J, helocobacter pylori Scan. J. Gasteroenterol. 1995, 30 suppl 208: 33-46
3. Marshall BJ, et al, pyloric camplylobacter infection and gastroduodenal disease. Med.J. Aust. 1985, 142: 439-444.

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