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IVD

H.Pylori Antigen Rapid Test kit (Colloidal Gold)

Instruction for Use

Read this instruction carefully before use

A rapid test for the qualitative detection of H.Pylori Antigen in human fecal specimens.

For professional medical institutions use only,Not for self testing.

PRODUCT NAME

H.Pylori Antigen Rapid Test kit(Colloidal Gold)

SPECIFICATION

25 tests/kit, 5 tests/kit, 1 test/kit

INTENDED USE

The H. pylori Ag Rapid Test 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 H. pylori Ag Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

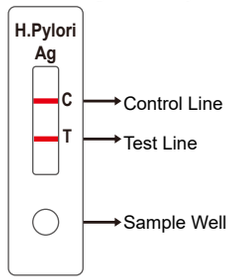
SUMMARY AND EXPLANATION THE TEST

Helicobacter pylori is associated with a variety of gastrointestinal diseases including non-ulcer dyspepsia, duodenal and gastric ulcers and active, chronic gastritis. 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 through the ingestion of food or water that is tainted with fecal matter. Antibiotics in combination with bismuth compounds have been shown to be effective in treating active H. Pylori infection..H. pylori infection is currently detected by invasive testing methods based on endoscopy and biopsy (i.e. histology, culture) or non-invasive testing methods such as urea breath test (UBT), serologic antibody test and stool antigen test. UBT requires expensive lab equipment and consumption of a radioactive reagent. Serologic antibody tests do not distinguish between currently active infections and past exposures or infections that have been cured. The stool antigen test detects antigen present in the feces, which indicates an active H. pylori infection. It can also be used to monitor the effectiveness of treatment and the recurrence of an infection.The H. pylori Ag Rapid Test uses a colloidal gold conjugated monoclonal anti-H. pylori antibody and another monoclonal anti-H. pylori antibody to specifically detect H. pylori antigen present in the fecal specimen of an infected patient. The test is user friendly, accurate, and the result is available within 15 minutes.

PRINCIPLE

The H. pylori Ag Rapid Test 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 colloidal gold (anti-H.p. conjugates) and 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre- coated with another monoclonal anti-H. pylori antibody, and the C line 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. pylori antigens, 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 line, indicating an H. pylori positive test result. Absence of the T line suggests that the concentration of H. pylori antigens in the specimen is below the detectable level, indicating an

H. pylori negative test result.The test contains an internal control (C line) which should exhibit a burgundy colored line of the immunocomplex of goat anti-mouse IgG/mouse IgG-gold conjugate regardless of the color development on the T line. If the C line does not develop, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

Components	25 tests/kit	5 tests/kit	1 test/kit
Cassettes	25 cassettes with dependent sealed foil pouch	5 cassettes with dependent sealed foil pouch	1 cassette with dependent sealed foil pouch
Sample Diluent Solution	1mL/bottle, 25pcs	1mL/bottle, 5pcs	1mL/bottle, 1pcs
Transfer tube	25 pcs	5 pcs	1 pcs
Package insert	1 pcs	1 pcs	1 pcs

MATERIALS REQUIRED BUT NOT PROVIDED

Timer for timing 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 expired devices.
4.Bring all reagents to room temperature (15°C-30°C) before use.
5.Do not use the components in any other type of test kit as a substitute for the components in this kit.
6.Do not use hemolized blood specimen for testing.
7.Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8.Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
9.Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
10.Dispose of all specimens and materials used to perform the test as biohazardous waste.
11.Handle the Negative and Positive Control in the same manner as patient specimens.
12.The testing results should be read within 25 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 25 minutes may give erroneous results.
13.Do not perform the test in a room with strong air flow, ie. electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

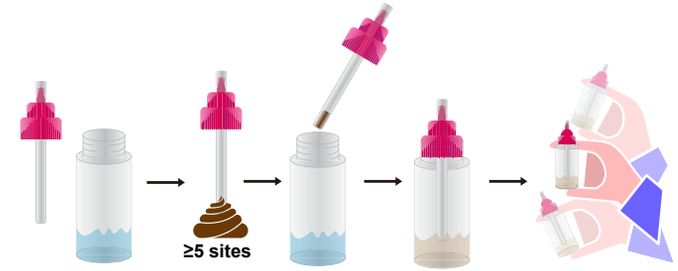
All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. The positive and negative controls should be kept at 2°C-8°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date 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.

Procedure A: Solid stool samples

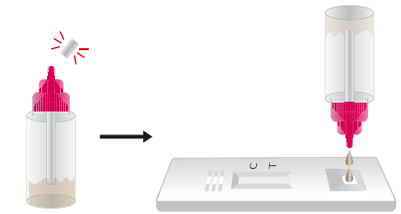
Step 1: Collect a random stool sample in a clean, dry receptacle.
Step 2: Open the stool collection device by unscrewing the top and use the collection stick to randomly pierce the stool sample in at least five different sites. Do not scoop stool sample as this may lead to an invalid test result.
Step 3: Ensure stool sample is only in the grooves of the collection stick. **Excess stool sample may lead to an invalid test result.**
Step 4: Replace the collection stick and tighten securely to close the stool collection device.
Step 5: Shake the stool collection device vigorously.



Note: Specimens extracted may be stored at 2-8°C for up to 3 days. If longer storage is required, freezing at ≤-20°C is recommended.

ASSAY 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 device. Place the test device on a clean, flat surface.
Step 3: Shake the stool collection device vigorously to ensure an effective liquid suspension.
Step 4: Position the stool collection device upright and twist off the dispenser cap. Holding the stool collection device vertically, dispense 2 drops of the solution (85-95uL) into the sample well of the test device. Do not overload sample.



Step 5: Set up timer.
Step 6: Results can be read after 15 minutes. Positive results can be visible in as short as 1 minute.
Don't read results after 30 minutes.To avoid confusion, discard the test device after interpreting the result.

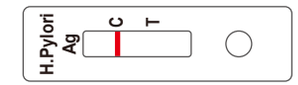
QUALITY CONTROL

Internal Control: This test contains a built-in control feature, the C band. The C line develops after adding specimen and sample diluent. Otherwise, review the whole procedure and repeat test with a new device.
External Control: Good Laboratory Practice recommends using the external controls, positive and negative, to assure the proper performing of the assay, in 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 fall outside of 2 -30℃.
e.The temperature of the test area falls outside of 15℃ -30℃.

INTERPRETATION OF ASSAY RESULT

Negative Control

If only the C line is developed, the test indicates that no detectable H. pylori antigen is present in the specimen. The result is negative.

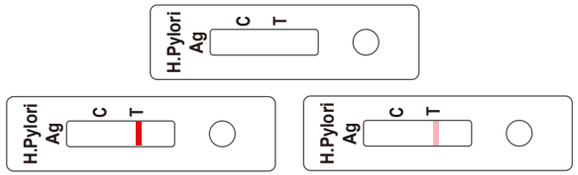


Positive Control:

If both C and T lines are developed, the test indicates the presence of H. pylori antigen

in the specimen. The result is positive.
Samples with positive or reactive results should be confirmed with alternative testing method(s) such as ELISA or PCR and clinical findings before a diagnostic decision is made.

INVALID:
If no C line is developed, the assay is invalid regardless of any color development on the T line as indicated below. Repeat the assay with a new test device.
Excess fecal specimen can lead to invalid test results; if this is the cause, re-sample and re-test (see instructions for collection of specimen).
The appearance of any burgundy color in the test bands, regardless of intensity, must be considered as presence of the band.



PERFORMANCE CHARACTERISTICS

1. Clinical Performance:

324 fecal samples collected from subjects with symptomatic gastrointestinal disorders and non-gastrointestinal symptoms were tested with the H. pylori Ag Rapid Test and with the UBT as reference test. A comparison of the results for all subjects is shown in the following table:

	H. pylori Ag Rapid Test		
BESTest	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%.			

2. Analytic Sensitivity:

The detection limit for the H. pylori Ag Rapid Test is 5 ng/ml of H. pylori lysate. Fecal specimen extractions containing 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 an assay time extended beyond 15 minutes.
The following experiments were done to validate the sensitivity of the H. pylori Ag Rapid Test:
Normal fecal specimen extractions 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 H. pylori Ag Rapid Test. Results are shown in the table below:
n=20 Relative Sensitivity at 5 ng/ml = 20/20 x 100% = 100%

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

LMITATIONS OF TEST

1.The Assay Procedure and the Interpretation of Assay Result sections must be followed closely when testing for the presence of H. pylori antigen in feces. Failure to follow the procedure, particularly the Specimen Collection procedure, may cause inaccurate results.
2.The H. pylori Ag Rapid Test is limited to the qualitative detection of H. pylori antigen in human fecal specimen. The intensity of the test line does not have a linear correlation with the antigen titer in the specimen.
3.A negative result for an individual subject indicates the 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 if the antigens that are detected are not present in the fecal sample collected.
5.If symptoms persist and the result from the H. pylori Ag Rapid Test is negative or non-reactive, it is recommended to re-sample the patient a few days later or test with alternative test methods.
6.The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings..

CAUTION

1.This product is used for in vitro diagnosis only.
2.Must strictly follow the instructions for operation and interpretation of the results.
3.The product is qualitatively tested, and the result cannot be used as a quantitative basis.should be tested using reagents within the validity period.
4.The cassetes, collectors,droppers,and tubes are for single person one-time use, cannot be reused.
5.Because the sample titer is different, the red lines of the test line will show different shades of color, all of which indicate positive results. The depth of the test line color cannot be used as the basis for determining the antibody titer in the sample.
6.The samples stored at low temperature should be balanced to room temperature and fully mixed before testing.
7.Samples and waste must be treated as a potential source of infection and the desiccant in the foil bag is not edible.

SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
LOT	Batch code	IVD	In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don't use the product when the package is damaged		Keep dry
	Date of manufacture	Σ	Tests per kit
CE	CE Mark		Biological Risks
EC REP	Authorized representative in the European Community		

BASIC INFORMATION

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