H.Pylori Antibody Rapid Test Cassette (Colloidal Gold)

Cassette

Instruction for Use

A lateral flow immunochromatographic assay for the qualitative detection of antibodies to Helicobacter Pylori (H. Pylori Ab) in human whole blood, serum or plasma.

CE IVD REF

In Vitro Diagnosis
For Professional Use

PACKAGING SPECIFICATION

1T/box,10T/box,20T/box,25T/box,40T/box,50T/box

INTENDED USE

The H.Pylori Antibody Rapid Test Cassette (Colloidal Gold) is a lateral flow immunochromatographic assay which uses recombinant antigens to detect the antibodies (IgG, IgM, and IgA) to H. Pylori in human whole blood, serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Helicobacter Pylori (H.Pylori).The test is recommended for professional use only. All results must be interpreted together with other clinical information available to the physician.

SUMMARY

Helicobacter Pylori is a corkscrew-shaped, gram-negative rod that lives in the mucous layer of the stomach. H. Pylori infection is now accepted as the most common cause of gastritis, and is etiologically involved in gastric ulcer, duodenal ulcer, gastric adenocarcinoma and primary gastric B-cell lymphoma.The organism is very common, infected at least half of the world's population. H. Pylori infection is typically acquired in childhood. Once acquired, infection persists chronically, probably continuing in the stomach throughout life. The damage to gastric structure and function of stomach is constant and direct. Approximately one in six of H.Pylori infection develops peptic ulcer disease and a small portion of H. Pylori infection leads to gastric cancer. The diagnostic tests for H.Pylori can be classified into two categories: Invasive and Noninvasive tests. Direct detection by invasive test procedures requires an endoscopy and biopsy specimens from antrum and stomach body. The presence of H. Pylori is then confirmed by direct culture, histological examination or rapid urease test. The endoscopy and biopsy specimens offer direct detection of active H.Pylori infections. Although the procedure is highly specific and high positive predictive value, the cost and discomfort to the patients are very high.The most widely available noninvasive test is probably the serological based test. The serology test detects H. Pylori specific IgG antibody in patient serum with current or prior infection. Serology test is a simple, convenient test with relative high sensitivity.The H.Pylori Ab Rapid Test is an immunochromatographic assay that uses specific antigen-coated colloidal gold to detect the presence of H. Pylori antibodies. The test is simple and easy to perform and the test results can be visually interpreted within 20 minutes.

PRINCIPLE

The H.Pylori Antibody Rapid Test Cassette is a lateral flow immunochromatographic assay using recombinant antigens to detect the antibodies (IgG, IgM, and IgA) to H. Pylori in human whole blood, serum or plasma. The membrane strip of the test cassette consists of: 1) a conjugate pad (sample pad); 2) a nitrate membrane strip containing a control line (C) and a test line (T). Both lines are not visible before performing the assay; When a sufficient specimen is added into the sample well, it will migrate by capillary action across the membrane strip. If increased level of antibodies (IgG, IgM, and IgA) to H. Pylori is present in the specimen, within the test window, a pink colored conjugated immunocomplex formed test line (T) will appear and it indicates a positive result. If the test line (T) does not appear, it indicates a negative result. The test contains an internal control line (C) which should appear as a red line regardless of color development on the test line (T). Otherwise, the test result is invalid and the assay shall be repeated with another test device.

MATERIALS SUPPLIED

Test devices. Each test cassette is packed in a foil pouch with a package of desiccant.
Assay buffer
Instruction for use.
Dropper

MATERIALS REQUIRED BUT NOT SUPPLIED

Timer
Clean containers for the collection of specimen

PRECAUTIONS

1. For professional and IN VITRO diagnostic use only.
2. The test should remain in the sealed pouch until use.
3. Do not use the kit if the foil pouch is punctured or not well sealed.
4. Do not reuse or use kits after the expiration date.
5. Do not mix components from kits with different lot number.
6. Avoid microbial contamination of reagents.
7. Wear gloves during the whole process and avoid reagents or specimen spilling-out. Wash hands thoroughly afterwards.
8. Dispose the used kit after decontamination of all liquids or solid wastes by following the local law or laboratory rule.
9. The testing results should be read within 15-20 minutes after a specimen is applied to the sample well or sample pad of the device. Read result after 20 minutes may give erroneous results.

STORAGE AND STABILITY

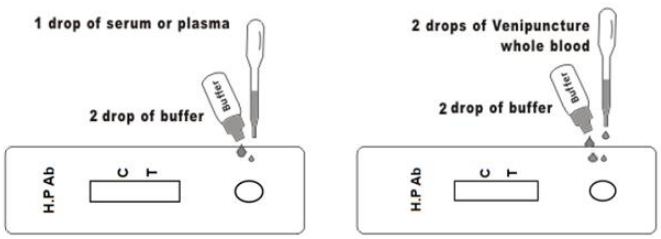
Store the kit in cool and dry places at a temperature between 2-30° C. **Do not freeze.**The shelf-life of the kit under these storage conditions is 24 months.

SPECIMEN COLLECTION AND PREPARATION

The H. Pylori Antibody Rapid Test can be performed using whole blood, serum or plasma.
1. Whole blood collected by venipuncture should be stored at 2-8 ℃,if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8° C for up to 3 days.For long-term storage, specimens should be kept below -20° C.
4. Bring specimens to room temperature prior to testing.Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, they should be packed in compliance with national regulations covering the transportation of etiologic agents.

TEST PROCEDURE

Test device, patient's samples, and controls should be brought to room temperature (10-30℃) prior to testing. Do not open pouches until ready to perform the assay.
1. Remove the test device from the foil pouch and place it on a clean and level surface. Be sure to label the device with specimen's ID number.
2. For whole blood specimen:
Hold the dropper vertically and transfer 2 drops of whole blood (approximately 50 μL) into the specimen well, then add 2 drop (about 80 μL) of buffer into the sample well, and start the timer. See illustration below.
3. For serum or plasma specimen:
Use a pipette or a dropper to withdraw specimen from the specimen collection container and dispense 1 drop (about 25 μL) into the sample well of the test device and then add 2 drop (about 80 μL) of buffer.
4. Start the timer and wait for the red line(s) to appear. The result should be read in 15 minutes. Don't read result after 20 minutes.



INTERPRETATION OF RESULT

(Please refer to the above illustration)

NEGATIVE: Only the C line appears, and no T line developed.
POSITIVE: Both C and T lines appear, the result is positive.
The intensity of the test line ("T") may be less than that of the control line ("C"); this still means positive result.
Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.
INVALID: No C line appears, regardless the color of T line. The assay is invalid. Repeat the assay with a new device. If the problem persists, contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered as an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATION OF PROCEDURE

1. Failure to follow the procedures of assay and test result interpretation may give inaccurate results.
2. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
3. The H. Pylori Antibody Rapid Test is limited to the qualitative detection of IgG, IgM, and IgA anti- H. Pylori in human whole blood, serum or plasma.
4. A negative result for an individual subject indicates absence of detectable antibodies to H. Pylori, but it does not preclude the possibility of exposure to or infection with H. Pylori.
5. A negative result can occur if the quantity of the antibodies to H. Pylori present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
6. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of H. Pylori infection.

PERFORMANCE

Clinical performance:
To have clinical study on the sensitivity and specificity of H. Pylori Antibody rapid test relative to a leading commercial rapid test, 420 samples from patients were studied. The results are shown in below table 1.
Table 1:

Relative Evaluation Result		Commercial H. Pylori Ab rapid test		Total Results
		Positive	Negative	
H.Pylori Ab Rapid Test	Positive	153	3	156
	Negative	4	260	264
Total Results		157	263	420

The study demonstrated below results for H. Pylori Antibody Rapid Test:
Sensitivity = 153/ (153+4) ×100% = 97.45%
Specificity = 260/ (3+260) ×100% = 98.86%
Accuracy= (153+260)/ (153+4+3+260) ×100% =98.33%

Precision
Intra-Assay
Within-run precision has been determined by using 10 replicates of four specimens: a negative, a low positive, a medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified >99% of the time.
Inter-Assay
Between-run precision has been determined by 10 independent assays on the same four specimens: a negative, a low positive, a medium positive and a high positive. Three different lots of the H. Pylori Antibody rapid tests have been tested using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified >99% of the time.
Cross-reactivity
Sera containing known amounts of antibodies to H. Pylori have been tested with Hepatitis A, B, C, E, HIV and Syphilis. No cross-reactivity was observed, indicating that the H. Pylori Antibody rapid test has a high degree of specificity for antibodies to H. Pylori.

Interfering Substances
The H. Pylori Antibody rapid test has been tested for possible interference from visibly hemolyzed and lipemic specimens, as well as serum specimens containing high bilirubin levels. In addition, no interference was observed in specimens containing up to 1,000mg/dL hemoglobin; up to 1,000 mg/dL bilirubin; and up to 2,000 mg/dL human serum albumin.

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Code:GKPD023-1 Effective date: May 28, 2024

Index of Symbols

IVD	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
2℃ 30℃	Temperature scope within which the product is reserved	LOT	Batch number
REF	Catalog #	Σ	Tests / box
EU REP	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

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