Helicobacter Pylori Antibody Rapid Test Kit

(Immunochromatography)

Product Name

Helicobacter Pylori Antibody Rapid Test Kit (Immunochromatography)

Intended Use

The reagent is used to detect the HP antibody in serum / plasma qualitatively.

Helicobacter Pylori (HP) grows in gastric mucus deep layer, surface of gastric mucosa, and mostly in gastric antrum, gastric pit, epithelial deep fold and gland cavity. There will be a short-term acute gastritis symptom with epigastric pain, nausea, emesis and flatulence after helicobacter pylori enter the stomach. The most common infection is chronic gastric inflammation with no obvious symptoms, which will cause uodenal ulcer and gastric ulcer. HP is a pathogenic factor of stomach cancer, for causing Induction of bacterial proliferation, Changes of gastric mucosa, decrease of hydrochloric acid in gastric juice. Over 90% of uodenal ulcer is found with HP, over 70% of gastric ulcer is found with HP and over 60% of chronic gastritis is associated with HP.

Test Principle

The test utilizes antibodies including a anti-human antibody and Rabbit anti-HP antibody (polyclonal antibody) on the nitrocellulose membrane with colloidal gold marked HP antigen as an mark tracer. The reagent is used to detect the HP in serum / plasma according to the principle of double antibody sandwich method and gold immunochromatography assay.

Main Components

Basic components: Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board. Colloidal gold marked pad coated with HP antigen, nitrocellulose membrane coated with anti-human antibody，control line coated with goat rabbit anti-HP antibody. The sample dilution is made of 20mM phosphate buffer (PBS).

Materials required but not provided: disposable pipette tips (depend on customer's requirement)

Description: different components of different batches cannot be used at the same time to avoid erroneous results

Storage and Expiry

Store as packaged in the sealed pouch at 4-30°C, avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw.

Sample Requirement

1. The reagent can be used for the serum and plasma samples.

2. A serum / plasma sample must be collected in a clean and dry container. EDTA, sodium citrate, sodium oxalate, heparin can be used as the anticoagulants.

3. Samples may be stored at 2-8℃ for 1 week prior to assay, and at -20 ℃ for 2 years. Frozen refrigerated samples should be recovered to room temperature before detection and thoroughly mixed. Repeat freeze and thaw for no more than 3 times. Samples exhibiting visible precipitates, stink or muddy should not be used. Centrifuged, filtered, or allowed to settle to obtain a clear sample for testing.

Test Methods

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20℃-30℃) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity: 20%~90%, Temp: 10℃-50℃)

Strip and Cassette:

1. Take off the outer packing, put the strip/cassette onto the desk with the sample adding area of the strip/ sample hole of the cassette up.

2. Drop 1 drop (25μl) serum or plasma vertically into the sample adding area of the strip /sample hole of the cassette. Add 2 drops (80-100ul) of sample buffer into the sample adding area of the strip / sample hole of the cassette.

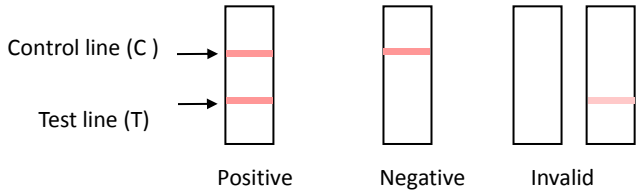
3. Observe the test results immediately within 15-20 minutes, the result is invalid over 20 minutes.

Result Judgment

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

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

INVALID: No red lines appear or control line fails to appear, indicating that the operator error or reagent failure.



Limitations

1. This reagent is designed for the qualitative screening test. Concentration of HP cannot be determined by this qualitative test.

2. The results of the reagent are only for clinical reference, which is not the only basis for clinical diagnosis and treatment. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.

3. Positive results indicating the presence of gastric helicobacter pylori antibody, but it can't determine whether gastric helicobacter pylori has led to the gastritis, gastric ulcer or the duodenal bulb ulcer. A confirmed diagnosis of gastritis, gastric ulcer or the duodenal bulb ulcer must be made with the clinical symptoms and other diagnostic techniques.

4. Negative result does not completely ruled out gastric helicobacter pylori infection, it only indicate that the specific antibodies of the stomach helicobacter pylori does not exist or the concentration is below detection limit. When HP infection is still suspected, a bacterial culture or histological analysis diagnosis is suggested.

Performance Characteristics

1. Using internal quality control samples:

Negative specificity: The results should all be negative when detecting 10 kits of HP negative quality control samples.

Positive specificity: The results should all be positive when detecting 10 kits of HP positive quality control samples.(Including strong, medium and weak positive samples)

Limit of detection: The results should all be positive when detecting diluted HP positive quality control samples with the diluent rate at 1:8.

Repeatability: The results should be consistent and the coloration degree should be consistent when detecting the precision control samples by 10 kits of the same batch.

2. Clinical trial results

A clinical evaluation was conducted on 1050 samples comparing the results obtained using the Helicobacter Pylori Antibody Rapid Test Kit (Colloidal Gold) and other commercially available HP tests. The results demonstrated a 99.38% positive agreement, 99.17% negative agreement, and a 99.24% overall agreement of the Helicobacter Pylori Antibody Rapid Test Kit (Colloidal Gold) when compared to the other HP tests.

3. Analytical sensitivity: 1000 mol/L bilirubin, 5.65mmol/L triglyceride, 6.5g/L hemoglobin has no effect on the detection result. The reagent is not affected by the rheumatoid factor, non-specific IgG and IgM. The addition of campylobacter jejuni , moscow' paratyphi B, common Bacillus, escherichia coli, hepatitis B virus, hepatitis A virus, hepatitis C virus, syphilis, human immunodeficiency virus samples showed no cross-reactivity.

4. Hook effect: the hook effect will not occur even diluents rate is 1:1024.

Precaution

1. For IN VITRO diagnose only.

2. Do not use after the expiration date.

3. The test result is invalid over 20 minutes.

4. The strength of the quality control line doesn’t indicate the quality problem of the reagent, a test result that is clearly visible demonstrates the reagent is effective.

5. All samples and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use.

6. Patients used to receive monoclonal antibodies therapy may have human anti-mouse antibodies in blood, which does not apply to the detection of this reagent. Other detection method is suggested.

7. Do not use other kinds of quality control sample to test the reagent. Components of different batches cannot be exchanged for use to avoid erroneous results.