Diagnostic Kit for Helicobacter pylori Antigen

(Immunochromatography)

Product Name

Diagnostic Kit for Helicobacter pylori Antigen (Immunochromatography)

Intended Use

The reagent is used to detect the HP antigen in human feces 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 duodenal 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 duodenal 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 HP polyclonal antibody and rabbit anti-mouse IgG antibody (polyclonal antibody) on the nitrocellulose membrane with colloidal gold marked HP antibody as an mark tracer. The reagent is used to detect the HP antigen in sample according to the principle of double antibody sandwich method and gold immunochromatography assay.

Main Components

The testing kit is in the form of strip and cassette. Basic components: Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board. Colloidal gold marked pad coated with HP polyclonal antibody, nitrocellulose membrane coated with anti-HP polyclonal antibody， control line coated with goat anti-mouse antibody. The sample dilution is made of phosphate buffer (PBS).

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

Sample Collection

1. The reagent can be used for the feces samples.

2. Enough sample (Solid 1-2 g or liquid 1-2 ml) must be collected in a clean and dry container.

3. Test immediately after sample collection. Samples may be stored at 2-8℃ for3 days prior to assay, and at -20 ℃ for 1 year.

4. Use the fresh samples. Samples which repeat freeze and thaw for many times can not be used,

Sample Handling

1. Frozen refrigerated samples should be recovered to room temperature before detection and thoroughly (20℃~30℃).

2. The samples were collected by the swab on the tube (50 mg).If the feces is in liquid state, add 50μL

3. Add the distilled water to the sample and mix sufficiently, the mixed sample must be tested in 1 hour.

Test Procedure

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. Break off the top of the sample tube, drop 3 drops (80-100μl) of diluted sample vertically into the sample adding area of the strip /sample hole of the cassette.

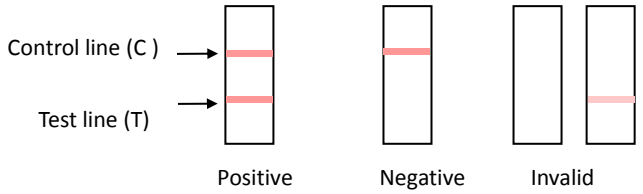
3. Observe the test results immediately within 10-15 minutes, the result is invalid over 15 minutes.

Result Judgment

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and the other 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. Verify the test procedure and repeat the test with a new testing device.



Limitation

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. 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: When detecting HP S1, S2 and S3 quality control samples, the results of S1 should all be positive, result of S2 should be positive or negative, the result of S3 should all be negative.

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. Analytical sensitivity:

2.1 Cross reaction: 10^7 cuf/mL staphylococcus aureus, pseudomonas aeruginosa, enterococcus faecalis , group C streptococcus , klebsiella pneumonia, branhamella catarrhalis, haemophilus influenza, monilia albican , neisseria meningitidis , shigella, neisseria gonorrhoeae , group B streptococcus, bacillus proteus vulgaris , S. faecium , bacillus mirabilis, acinetobacter , bacillus ex pneumoenteritidis suis, gardnerella vaginalis, acinetobacter calcoaceticus, escherichia coli, pathogenic escherichia coli, salmonella enteritidis, chlamydozoa trachomatis, adenovirus and rotavirus group samples showed no cross-reactivity.

2.2 Interference factor: 600 mol/L bilirubin, 5g /L triglyceride, 10g/L hemoglobin and 10g/L oxalic acid have no effect on the detection result.

3. Clinical Performance

A total of 1148 samples from susceptible subjects were tested by the Troponin I Rapid Test and by method of EIA. Comparison for all subjects is showed in the following table:

	EIA		
Rapid Test	**Positive**	**Negative**	**Total**
Positive	462	3	465
Negative	2	681	683
Total	464	684	1148

Relative Sensitivity: 99.57% , Relative Specificity: 99.56%, Overall Agreement: 99.56%

Precaution

1. For IN VITRO diagnose only. Reagents should be used as soon as possible after opened.This reagent cannot be reused for disposable.

2. 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.

3. Effective measures must be taken to protect the sample during the collection to reduce the nosocomial infection.

4. Reagent blocking by sample may occur according to too much or too sticky sample. Diluted samples should be centrifuged, filtered, or allowed to settle to obtain a clear sample for testing..

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

6. 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.