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CE IVD REF

H. Pylori (HP) Antigen Rapid Test

【For the qualitative detection of H. Pylori Antigen in faeces】

(Single use test cassette)

The instruction must be read carefully and completely prior to the use of HP Ag Rapid Test. Instruction must be followed carefully. If directions are not followed exactly, inaccurate test result may occur.

INTENDED USE

The kit is for the detection of H. Pylori Antigen (HP Ag) in human faeces.

PRINCIPLE

The kit uses double antibody sandwich method and colloidal gold immunoassay, which uses nitrocellulose filter membrane coated with HP antibody, colloidal gold labeled HP antibody and other reagents. When the test is performed, if the sample is positive, the HP antigen in the sample can bind to the gold-labeled HP antibody to form a complex. As the complex moves forward along the test strip by chromatography, it will then bind to the antibody coated by the test line to form the gold-labeled antibody ~HP antigen ~ antibody compound and agglutinate for color display. There is a quality control line on the nitrocellulose filter membrane as the control, so when there is a red quality control line and a red reaction line, it is positive. When there is no HP Ag in the sample to be tested only a red quality control line is negative. As a quality control, no matter the result is positive or negative, a red quality control line will appear. If no red quality control lines , the experiment is invalid.

REAGENTS AND MATERIALS PROVIDED

Each kit contains:

1. Test cassettes (individually pouched)
2. Each pouch contains one cassette, one desiccant bag
3. Sample collection tube (with diluent buffer)
4. Instruction for use

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer or stopwatch
2. Biohazard disposal container
3. Disposable gloves

WARNING

For in vitro diagnostic use ONLY

Read the package insert completely before use. It is very important that the correct procedure is followed. Fail to add the patient sample may lead to a false negative result (i.e. a missed positive).

PRECAUTIONS

1. The kit is a disposable product, only for external diagnosis.
2. All the waste and specimen should be treated in case of transmitting disease and must be properly disinfected (autoclaving is preferred) before disposal.
3. Make sure the test is not expired (EXP Date is indicated on the kit box).
4. Do not use the test if the pouch has been perforated.
5. Do not modify the test procedure.
6. Each test is for single use only.
7. Always interpret the results under good light conditions to avoid misreading of the results.
8. Different batch of product components cannot be mixed.
9. If desiccant bag is not present in the pouch, DO NOT USE the test.
10. Always add accurate volume of specimen by following the instruction.
11. The test cassette must be used directly after unsealing. It is not allowed to divide it for use.
12. Observe the result in 15 minutes. Please strictly observe the interpretation time.
13. If the reagent is stored in the refrigerator (2~8℃), it should be restored to room temperature in advance (about 30 minutes). After the test preparation is done, the pouch can be open to avoid the test reagent being affected by moisture and affecting the test results.

STORAGE

The kit should be stored at room temperature (2-30°C, do not freeze) for 24 months from the date of manufacture. Keep the test cassette in sealed pouch until use. Once you have taken the test cassette out of the pouch, perform the test as early as possible (within 1 hour) to avoid test cassette from becoming moist. Do not use the test beyond the indicated expiration date.

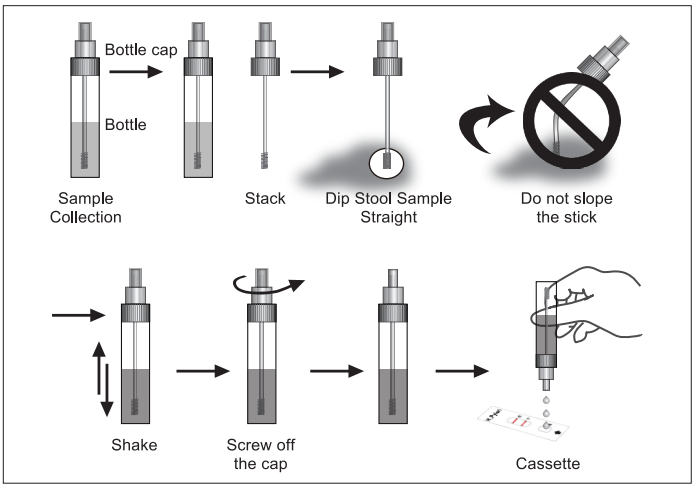
The diluent buffer should be stored at room temperature (2-30°C, do not freeze).

SPECIMENS COLLECTION AND STORAGE

1. The samples should be fresh. If the samples cannot be tested immediately, they can be stored for 1-2 days in 2~8°C and 3 months in -20°C.
2. Randomly collect samples in a clean, dry container.
3. Unscrew the cap of the sample collection and take the collection stick out. Be careful not to spill the solution out of the bottle
4. Random sampling at several different locations on the sample with a sample collection stick (or 20~50mg of feces

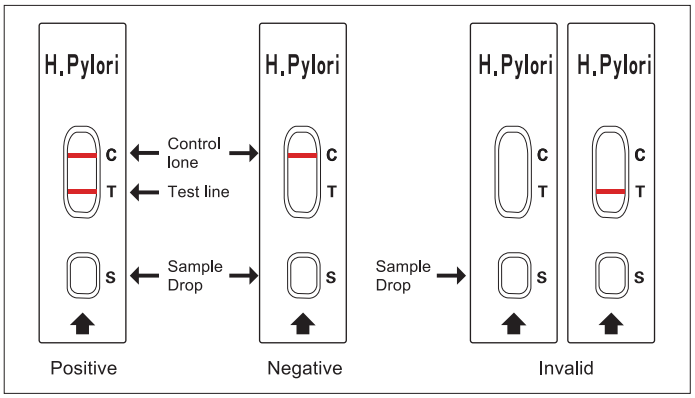
with a sample collection tube).
5. If the sample is a diarrhea-like fluid sample, can absorb about 50 μL of samples for testing.

ASSAY PROCEDURE



1. Insert the sample collection stick into the sample collection tube, tighten the cap, and shake it vigorously to ensure the sample and solution is well mixed.
2. Tear off the pouch to take out the detection reagent, take off the cap of the sample collection tube, and add 2~3 drops (80~100 μL) of sample liquid into the sample hole of the detection cassette.
3. Observe the result in 15 minutes.

INTERPRETATION OF RESULTS



Note: 'C' – Control line; 'T' –Test line

1. ***Negative:*** No red lines appear in the test zone (T) in 15 minutes only a red line show in the control zone (C), indicates that no HPAg have been detected with this test. However, this does not exclude the possibility from infection with H. Pylori.
2. ***Positive:*** One red line show in the control zone (C) and one red line in the test zone (T). It indicates the specimen infect H. Pylori possibly, recommend further testing.
3. ***Invalid:*** No red lines appear in the control zone (C), regardless of whether there is a red line in the test zone (T), indicating that the test is invalid. Discard the test cassette and perform with new cassette.

Built-In Control

The kit has a built-in procedural control that demonstrates assay validity. If a red line appeared in the control zone (C), it indicates that the test runs correctly.

LIMITATION

1. The kit must be used in accordance with the instruction for use to obtain an accurate result.
2. The positive results suggest the presence of HP Ag in the specimen, and the intensity of the test line does not necessarily correlate with the HP Ag titer in the specimen. The kit is intended as an aid in the diagnosis of H. Pylori infection.
3. The negative results indicate that the absence of HP Ag or the concentration of antigens is too low to detect (i.e. window period of infection).
4. A person who has HP Ag is presumed to be infected with the virus. Additional testing and medical evaluation is required to determine the state or associated disease.

PERFORMANCE CHARACTERISTICS

1. ***Coincidence rate of positive reference materials:*** 3 positive reference materials were tested, and the results were all positive.
2. ***Coincidence rate of negative reference materials:*** 10 negative reference samples were tested and all the results were negative.
3. ***Minimum detection amount:*** Testing enterprises minimum detected quantity reference, the results should be positive.
4. ***Repeatability:*** 10 test cassettes were tested parallel with the precision reference of the enterprise, and the test results should be consistent and the color should be uniform.
5. ***Cross reaction:*** There is no cross reaction with normal appeared in the stomach - intestinal bacteria and some other common infections bacteria in the same area, such as salmonella enteritidis, salmonella porcine cholerae, klebsiella,vibrio cholera, shigella dysentery, E. coli,, E. coli, Vibrio parahaemolyticus, enterococcus, clostridium butyricum and bifidobacteria.
6. ***Clinical sample compliance:*** A total of 1020 clinical samples were tested for validation, of which 278 were positive and 742 were negative. The test results are as follows: The positive, negative and total coincidence rates were 93.9%, 97.3% and 96.4%. The consistency coefficient was K=0.909. It shows that the two reagents have good consistency.

Table 1

The inspection reagent (NewScen)	Contrast reagent (Hangzhou Aikang)		Total
	+	–	
+	261	20	281
–	17	722	739
Total	278	742	1020

Performance statistics are as follows:
Positive coincidence rate＝261 /278×100%=93.9%;
Negative coincidence rate＝722 /742×100%=97.3%;
Total coincidence rate＝(261+722)/1020 ×100%= 96.4%;
The consistency coefficient was K=0.909.

REFERENCE

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to invasive methods and evaluation of two new tests. Am J Gastroentero, 2001, 96: 353-366.

INDEX OF SYMBOLS

	Do not re-use
IVD	For In Vitro Diagnostic medical device
	Use by date
	Date of manufacture
2℃ 30℃	Temperature limitation
	Consult instructions for use
EC REP	Authorized Representative in the European Community
LOT	Batch code
CE	CE Mark
	Manufacturer

Product disclaimer: This product has been manufactured under strict GMP regulation to ensure the diagnostic accuracy of the test. It is out of control of the manufacture when the test is performed in diverse environment and by diverse group of individuals that may affect the results to a certain degree.

Note: The manufacturer, the distributor, or its associates will not be liable for any losses, claims, liability, costs or damages, whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether a positive or negative by use of this product.

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