NEWSCEN
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CE IVD REF

H. Pylori (HP) Antibody Rapid Test

【For the qualitative detection of H. Pylori Antibody in serum/ plasma and whole blood】

(Single use test cassette)

The instruction must be read carefully and completely prior to the use of HPAb 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 Antibody (HP Ab) in human serum/ plasma and whole blood.

PRINCIPLE

The kit is coated and labeled with HP recombinant antigen (chimed with HP cytotoxin-related gene (cagA) and vacA antigen fragment) using double antigen sandwich and colloidal gold immunoassay technology, as well as colloidal gold immunoassay diagnostic reagent made from other reagents. When the test is performed, if it is a positive sample, the HP antibody in the sample can bind to the colloidal gold-labeled HP antigen, due to the chromatography move forward along the test strip, combine with another HP antigen coated on the nitrocellulose filter membrane to form the gold-labeled antigen ~ anti-HP antibody ~ antigen compound and agglutinate the color. 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 Ab in the sample to be tested, only a red quality control line appear and the result is negative. As for quality control, no matter whether the result is positive or negative, a red quality control line will appear. If there is no red quality control line , 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 and one disposable plastic dropper
3. One bottle of 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. All the waste and specimen should be treated in case of transmitting disease and must be properly disinfected (autoclaving is preferred) before disposal.
2. Make sure the test is not expired (EXP Date is indicated on the kit box).
3. Do not use the test if the pouch has been perforated.
4. Do not modify the test procedure.
5. Each test is for single use only.
6. Always interpret the results under good light conditions to avoid misreading of the results.
7. Different batch of product components cannot be mixed.
8. If desiccant bag is not present in the pouch, DO NOT USE the test.
9. Always add accurate volume of specimen by following the instruction.
10. The test cassette must be used directly after unsealing. It is not allowed to divide it for use.
11. Observe the result in 20 minutes. Please strictly observe the interpretation time.
12. If the reagent is stored in the refrigerator (2~8℃), it should be restored to room temperature in advance.

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

Plasma

1. Collect whole blood into a collection tube (containing EDTA, Na-citrate or heparin) by venipuncture.
2. Separate the plasma by centrifugation.

Serum

1. Collect whole blood into a collection tube (containing no anticoagulants) by venipuncture.
2. Allow the blood to clot.
3. Separate the serum by centrifugation.

Avoid the use of hemolytic, turbid, microorganism contami-

nated specimens. Specimen should be stored at 2-8°C for 7 days or frozen at -20°C for maximum 3 months. Avoid specimen deterioration by multiple freeze-thaw cycles.

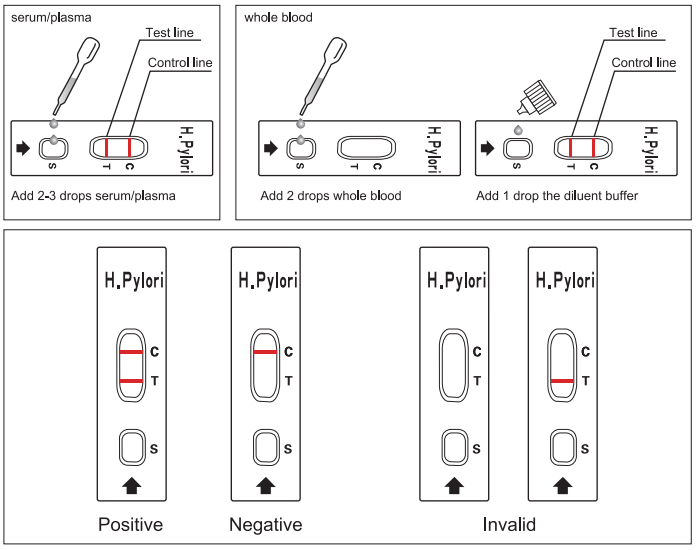
Whole Blood

Venipuncture whole blood collected into a collection tube (containing EDTA, Na-citrate or heparin) can be used immediately after collection or stored up to 7 days at 2-8°C.

ASSAY PROCEDURE

1. Place the test cassette on flat surface. Use it immediately once unsealed.
2. Serum or plasma testing: Add 2~3 drops (100~150μL) serum or plasma into the sample well(S).
3. Whole Blood testing: Add 2 drops (100~120μL) whole blood into the sample well(S), then add 1 drop of diluent buffer.
4. Observe the result in 20 minutes.

INTERPRETATION OF RESULTS



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

1. ***Negative***: No red lines appear in the test zone (T) in 20 minutes only a red line show in the control zone (C), indicates that no HP Ab 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. This test kit is limited to the qualitative detection of h. pylori antibodies in samples. Affected by the minimum detection limit of the product, negative results may be due to the concentration of antibodies in the tested sample below the minimum detection limit.
2.The kit must be used in accordance with the instruction for use to obtain an accurate result.
3. The positive results suggest the presence of HP Ab in the specimen, and the intensity of the test line does not necessarily correlate with the HP Ab titer in the specimen. The kit is intended as an aid in the diagnosis of H. Pylori infection.
4. The negative results indicate that the absence of HP Ab or the concentration of antigens is too low to detect (i.e. window period of infection).
5. A person who has HP Ab 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: 10 positive reference materials were tested, and the results were all positive.

2. Coincidence rate of negative reference materials: 20 negative reference samples were tested and all the results were negative.

3. Minimum detection amount: 3 samples of internal quality control sensitivity reference materials should be used for testing, L1 should be positive, L2 can be positive or negative, L3 should be negative.

4. Repeatability: 10 test cards were tested in parallel with reference materials of internal quality control blood liquidation repeatability of the enterprise, and the test results should all be positive with consistent color intensity.

5. Cross-reaction: Testing indicates that there is no cross-reaction to positive samples of human immunodeficiency virus, hepatitis B virus, hepatitis C virus and rheumatoid factor. The anticoagulants heparin, EDTA and sodium citrate, as well as the preservative sodium azide had no obvious effect on the specificity of the product. Samples with hemoglobin no higher than 5mg/mL, triglyceride no higher than 8mmol/L, bilirubin no higher than 300μmol/L and cholesterol no higher than 5mg/mL had no interference on the detection results.

6. Clinical sample compliance: A total of 1000 clinical samples were tested for validation, of which 295 were positive and 705 were negative. The test results are as follows: The positive, negative and total coincidence rates were 95.6%, 98.0% and 97.3%. The consistency coefficient was K=0.935. It shows that the two reagents have good consistency.

Table 1

The inspection reagent (NewScen)	Contrast reagent（Aikang）		Total
	+	−	
+	282	14	296
−	13	691	704
Total	295	705	1000

Performance statistics are as follows:
Positive coincidence rate＝282/295×100%=95.6%;
Negative coincidence rate＝691/705×100%=98.0%;
Total coincidence rate＝(282+691)/1000 ×100%= 97.3%.
The consistency coefficient was K=0.935.

REFERENCE

1. 吴宝山．幽门螺杆菌感染的诊断方法及意义．中级医刊,1997,32（6）：28.
2. 张卓然，主编．临床微生物学和微生物检验.北京：人民

卫生出版社，2004 年，第 3 版：271.
3.International Agency for Cancer Research Schistosomes, liver flukes and Helicobactor pylori. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, 1994, 61: 177 — 240.
4.Pi GH , He HY, Gu SY, Zhang SX , Deng Y. Detection of serum anti-HCV IgG by gold conjugated immunosorbent assay. Zhonghua Shiyan He Linchuang Bingduxue Zazhi , 1995 ;9 :371 – 373.

INDEX OF SYMBOLS

	Do not re-use
	For In Vitro Diagnostic medical device
	Use by date
	Date of manufacture
	Temperature limitation
	Consult instructions for use
	Authorized Representative in the European Community
	Batch code
	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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