HP Rapid Test Kit

Instruction for use

【Product Name】HP Rapid Test Kit

REF A10031001B, A10031001I, A10031001C, A10031001D, A10031001E

【Specification】1 test/kit, 2 tests/kit, 5 tests/kit, 10 tests/kit, 25 tests/kit

【Intended Use】

The HP Rapid Test Kit is a colloidal gold immunochromatography intended for the qualitative detection of the helicobacter pylori antigen in human feces. The test is intended as an aid in the diagnosis of H. pylori infection.

【Summary】

Helicobacter pylori is aspiral shaped bacterium that lives in the stomach and duodenum.H.pylori is a newly discovered stomach infection, which was first reported by Barry Marshall and Robin Warren of Perth,Western Australia,in 1983.The new bacterium lives in the stomach of stomach lining,a condition which is called “gastritis”. Gastritis is the underlying condition which causes ulcers, and other digestive complaints,possibly including cancer of the stomach. In fact, it is now clear that H.pylori is the principle etiologic agent in type B gastritis(chronic active antral gastritis) pathology for which it appears to be the triggering and perhaps aggravating factor. Increasing data are being accumulated regarding the fundamental role of H.pylori in active chronic gastritis, in gastric ulcer and in duodenal ulcer and its close correlation with gastric lesions.

【Test Principle】

The test is a sandwich immunoassay of double antibodies. If there are H.pylori antigen in the sample, it will be combined with colloidal gold labeled mouse anti-H.pylori antibody, form a complex. Under the action of chromatography, the complex flows on the nitrocellulose membrane. Then, the complex will combine to another H.pylori antibody (T line) coated on the nitrocellulose membrane. The control line (C line) must appear in the control area of the rod for the result to be valid. A line will appear in the test line area, indicating a positive result.

【Main components】

Materials Provided:

Specification / Material	1 test/kit	2 tests/kit	5 tests/kit	10 tests/kit	25 tests/kit
Test Cassette	1	2	5	10	25
Sample Diluent	1	2	5	10	25
Instruction for Use	1	1	1	1	1

Materials Required but not provided:

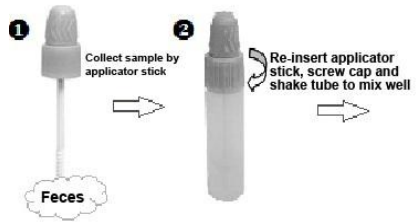
1.Timer
2.Pipette
3.Biohazard disposal container
4.Any necessary personal protective equipment

【Storage Conditions and Validity】

1.This product should be stored in a dark and dry place at 2~30℃.The validity period of the kit is 24 months.
2.After unpacking the aluminum foil bag of the test cassette, It should be used in the specified environment (Temperature 2-35°C,Humidity 40%-90%) within 1 hour.
3.Please see label for the information about the date of manufacture and shelf life.

【Samples collection Handing】

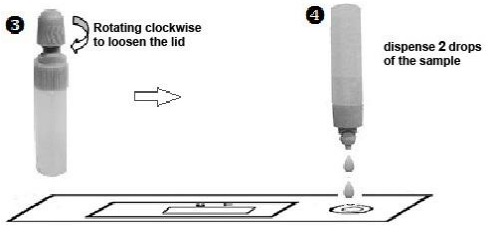
1. This kit is used to detect human feces samples. Other samples may not get accurate results.
2. Remove the applicator stick from the sample collection tube. Insert and turn the stick into the feces sample 5-6 times at different sites (fully covering the spiral groove on the applicator stick).
3. Re-insert the applicator stick into the sample collection tube, screw the cap and shake the tube vigorously to mix the sample well.
4. Testing should be performed immediately after the feces have been collected. If the feces cannot be processed immediately, it may be held at 2 ~ 8 ℃ for up to 48 hours.



【Test Method】

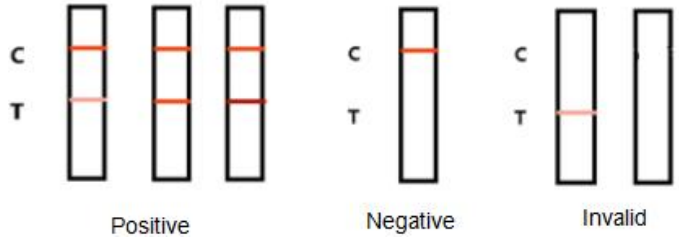
Note: Please read the Instruction for Use carefully before use. The test should be operated in room temperature.

1. Read package insert carefully before testing. Bring all test cassettes and samples to room temperature (10-30℃). Do not open pouches until ready to perform the assay.
2. Remove the test cassette from the foil pouch and place on a clean dry surface.
3. Rotating clockwise to loosen the lid of sample collection tube cap.
4. Invert the sample collection tube and dispense 2 drops of sample which has been mixed evenly and without bubble into the sample well on the cassette, start timing.
5. Interpret the test results at 15 minutes. Do not interpret the results after 20 minutes.



【Interpretation of Test Results】

Positive(+):There is coloration on line C,and a colored line appeared T line.
Negative(-): There is coloration on line C only showing as following picture
Invalid: There is no coloration on line C, as shown in the following pictures. The test is invalid or an error in operation occurred. Repeat the assay with a new cartridge.



【Reporting of Results】

Positive test:

If any Positive, there is currently a suspicion of H.pylori infection. Please carefully compare the above test results this time to more accurately determine which H.pylori is infected and contact your doctor or local health department immediately.

Negative test:

Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions, particularly in the presence of clinical signs and symptoms consistent with H.pylori infection. It is recommended that these results be confirmed by other methods, if necessary, for patient management Control.

Invalid:

If the control line C is not visible, the result is invalid. An invalid result may have been caused by the incorrect execution of the test. Please perform a new test with a new sample and a new test cassette. If the result is invalid again, you should consult a doctor or a test center.

【Limitation of The Test】

1. The kit can be used for the detection of human feces samples.The reliability of the determination of this substance in other types of samples has not been fully confirmed.
2. The kit will only indicate the presence of H.pylori in the specimen and should not be used as the sole criteria for the diagnosis of H.pylori infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. 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.
5. Following certain antibiotic treatments, the concentration of H.pylori antigens may decrease to the concentration below the minimum detection level of the test. Therefore, diagnosis should be made with caution during antibiotic treatment.

6. Other factors may interfere with Anbio HP Rapid Test Kit and may cause erroneous results. These include technical or procedural errors, as well as additional substances in feces specimens.

【Performance Characteristics】

1. **Sensitivity and Specificity**

The clinical performance of HP Rapid Test Kit was evaluated in comparison to biopsy results of human specimens. The results show that the clinical sensitivity of the HP Rapid Test Kit is 98.30% and the clinical specificity is 98.35%.

HP Rapid Test Kit	Biopsy results		
	Positive	Negative	Total
Positive	231(a)	2(b)	233(a+b)
Negative	4(c)	119(d)	123(c+d)
Total	235(a+c)	121(b+d)	356(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.30%	95.70%~99.53%	
Clinical specificity	98.35%	94.16%~99.80%	
Total coincidence rate	98.31%	96.37%~99.38%	

2. **Limitation of Detection (LoD)**

The LoD of HP Rapid Test Kit is 0.6 ng/mL.

3. **Cross-reactivity**

The HP Rapid Test Kit does not cross with the following common Potential Cross-Reactants.

S.N.	Potential Cross-Reactant	S.N.	Potential Cross-Reactant	S.N.	Potential Cross-Reactant
1	Acinetobacter baumannii	8	α-haemolytics streptococcus	15	Proteus vulgaris Hauser
2	Adenovirus	9	B-haemolytic streptococcus	16	Pseudomonas aeruginosa
3	Enterococcus faecalis	10	Klebsiella pneumonia	17	Rotavirus
4	Escherichia coli	11	Moraxella catarrhalis	18	Salmonella Paratyphi A
5	Gardnerella vaginalis	12	Neisseria gonorrheae	19	Salmonella Paratyphi B
6	Geotrichum candidum	13	Neisseria meningitides	20	Salmonella Paratyphi C
7	Haemophilus influenza	14	Proteus mirabilis	21	Salmonella typhi

4. **Interfering substances**

The following common and potentially interfering substances at the tested concentrations have no effect on the test results.

S.N.	Substances	Concentration	S.N.	Substances	Concentration
1	Stearic Acid	16 mg/g	6	Omeprazole	2 mg/g
2	Palmitic Acid	16 mg/g	7	Cimetidine	2 mg/g
3	Barium Sulphate	20 mg/g	8	Calcium Carbonate	20 mg/g
4	Human Haemoglobin	30 mg/g	9	Mucin	14 mg/g
5	Ranitidine Hydrochloride	2 mg/g	10	Human Blood	200 μL/g

【Precautions】

1. After opening the package, the kit should be ready for use as soon as possible and avoid placing it in a high temperature (over 30°C) and high humidity environment for a long time.
2. All samples and test cassettes after use should be considered potentially dangerous and should be treated as infectious materials, and the waste should be disposed of in accordance with the regulations of the hospital or environmental protection department.
3. The test strips with any color lines before the test should not be used and the cassettes with damaged packaging bags or invalid seals should not be used.
4. The kit is for in vitro diagnostic use only.The kit is for single-use,please do not use the product after it expires.
5. Do not mix components from different kit lots.

【Bibliography】

1. Marshall B.j.et al.Pyloric Campylobacter infection and gastroduodenal disease. Med. J. Aust.142:439-444(1985).
2. Lambert,D.J.,Lin,s.k. and Aranda-Michel,J.Helicobacter pylori, Scand. J . Gastroenterol .30 suppl 208:33-46(1995).
3. Evans,D.J.,Evans,D.G,Graham,D.Y.and Klein,P.D.A sensitive and specific serologic test for detection of Campylobacter pylori infection.Gastroenterology.96:1004-1008(1989).

【Index of Symbols】

IVD	In vitro diagnostic medical device		Do not re-use
EC REP	Authorized representative in the European Community/ European Union		Consult instructions for use or consult electronic instructions for use
	Caution		Manufacturer
30℃ 2℃	Temperature limit	LOT	Batch code
	Use-by date		Keep dry
	Keep away from sunlight	REF	Catalog number
	Date of manufacture	Σ	Contains sufficient for <n> tests
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		Do not use if package is damaged and consult instructions for use

【Basic Information】

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Email: peter@lotusnl.com

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CE IVD