Helicobacter pylori (H.pylori) IgG/ IgM Test Kit

(Colloidal Gold Method)

【Product Name】

Helicobacter pylori (H.pylori) IgG/ IgM Test Kit (Colloidal Gold Method)

【Introduction】

Helicobacter pylori (H.pylori) is a gram-negative microaerobic bacteria that parasitizes the stomach and duodenum. Its infection is very common, and the global natural population infection rate exceeds 50%. Factors affecting the rate of Helicobacter pylori infection include economic status, living conditions, education level, occupation and drinking habits, etc. Generally speaking, developing countries are higher than developed countries. It is currently believed that in the natural environment, humans are the only source of infection of Helicobacter pylori, and the route of transmission is presumed to be oral infection.

【INTENDED USE】

Babio®Helicobacter pylori (H.pylori) IgG/ IgM Test Kit (Colloidal Gold Method) is used for the in vitro qualitative detection of Helicobacter pylori antibody IgG/IgA in human serum/plasma/whole blood samples.

For people who have not been treated for Helicobacter pylori eradication, combined with clinical and other laboratory indicators, it is used for the auxiliary diagnosis of Helicobacter pylori infection.

Note: Antibody detection products cannot be used for the recent judgment of the evaluation of the eradication effect of Helicobacter pylori.

【Test Principle】

This kit uses the principle of colloidal gold immunochromatography technology.

【Reagents And Materials Supplied】

Component Name	1T/box	20T/box	25T/box	50T/box
Disposable Dropper	1	20	25	50
Sample Diluent	0.5ml	4ml	5ml	10ml
Desiccant	1	20	25	50
Disposable Test Card	1	20	25	50
Instruction Manual	1	1	1	1

【Materials Required But Not Supplied】

1. Lancets, sample collection and preparation device and disinfecting sterile wipes
2. Clock or timer

【Shelf Life and Storage】

1. Store in a dry place at 2～30 ℃ away from light.
2.Transport at 2-37℃ for 20 days
3. After opening the inner packaging, the test card will become invalid due to moisture absorption, please use it within 1 hour.
4. The shelf life of the test kit is 12 months from date of manufacture.

【Warnings and Precautions】

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Reason: MoldSign Signature
Location: Moldova

1. This kit is limited to the qualitative detection of Helicobacter pylori antibodies in human serum, plasma or whole blood.
2. For emergency and use by medical or health professionals only at designated point of care facilities.
3. Read the package insert in its entirety prior to performing the test. Failure to follow the package insert instructions may result in an invalid test result.
4. Handle specimens as if they contain infectious agents in accordance to standardized procedures, and OSHA standards on blood-borne pathogens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. Do not use it if the tube/pouch is damaged or broken.
7. Test is for single use only. Do not re-use under any circumstances.
8. Humidity and temperature can adversely affect results.
9. Do not use product after indicated expiration date.
10. Follow storage recommendations listed on the product labels. Storage and handling outside of these conditions may adversely affect product.
11. The personnel who performed the testing were blinded to the identity / code of the sample and the expected results.
12. Dispose of all samples and used test components in appropriately approved and labeled biohazard waste containers.
13. This kit will have a negative result under the following conditions: when the titer of the Helicobacter pylori antibody in the sample is lower than the minimum detection limit of this kit, or the Helicobacter pylori antibody has not yet appeared at the time of sample collection.
14. Samples containing higher titers of heterophilic antibodies or rheumatoid factors may affect the expected results.
15. For professional use only.

【Specimen Collection】

1. Serum (S): Collect whole blood into a collection tube (does not contain anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture, let it stand for 30 minutes for blood coagulation, and then centrifuge the blood to obtain the supernatant Serum specimen of liquid.
2. Plasma (P): Collect whole blood in a collection tube (containing anticoagulants, such as heparin, EDTA, and sodium citrate) by venipuncture, and then centrifuge the blood to obtain a plasma sample.
3. Whole blood (WB): Collect whole blood through a blood sampling device. WB can be transferred directly to the test card by pipetting.

【Test Procedure】

1.Before opening the bag, please leave it at room temperature. Take the test device out of the sealed bag and use it as soon as possible. The best results will be obtained if the measurement is performed within one hour.
2.Dispense 35 μL of serum/plasma or whole blood into the sample wells of the test card.
3.Dispense 1 drop of buffer directly from the buffer bottle, or use a calibrated pipette to transfer 40 μL of buffer to the sample well.
4.The result should be between 10 and 20 minutes, but not more than 30 minutes.

【Test Quality Control】

1. A procedural control is included in the test. A red line appearing in the control region is considered as an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

2. Control standards are not provided with this kit. It is recommended to follow good laboratory practice including adding positive and negative controls in order to verify proper test performance.

【Interpretation of Results】

NEGATIVE:

If only the quality control line C appears, and the test lines M and G are not purple/red, it indicates that no antibody is detected, and the result is negative.

POSITIVE:

IgM positive: If both the quality control line C and the test line M appear purple/red, it indicates that the Ig M antibody is detected, and the result is positive for Ig M antibody.

IgG positive: If both the quality control line C and the test line G appear purple/red, it indicates that the Ig G antibody is detected, and the result is positive for Ig G antibody.

IgM and IgG positive: If the quality control line C and the test lines M and G all appear purple/red, it indicates that the Ig M and Ig G antibodies are detected, and the result is positive for both IgM and IgG antibodies.

INVALID:

If the quality control line C is not displayed, the test result is invalid regardless of whether there is a purple/red test line, and it should be tested again.

【Performance Characteristics】

1. Cross-reaction

Helicobacter pylori (H.pylori) IgG/ IgM Test Kit (Colloidal Gold Method) has been tested for Campylobacter jejuni, Bacillus subtilis, Escherichia coli, Proteus vulgaris, Candida albicans, Enterococcus, Klebsiella, Helman's Helicobacter , Pseudomonas aeruginosa, Clostridium aeruginosa, Staphylococcus, Streptococcus pneumoniae, Salmonella typhi, Acinetobacter calcium acetate, Fusobacterium nuclei, Bacteroides fragilis (concentration is 10^7 CFU/mL). The result showed no cross-reaction.

2. Interfering Substances

The following compounds have been tested using the SARS-CoV-2 IgG/IgM Rapid Test Kit (Colloidal gold) and no interference was observed.

Triglyceride: 100 mg/dL; Ascorbic Acid: 20 mg/dL; Hemoglobin: 1000 mg/dL; Bilirubin: 60 mg/dL, Total cholesterol: 6 mmol/L.

3. Product compliance rate:

The sensitivity and specificity of H.pylori IgG/IgM Test Kit(Colloidal Gold Method) were 98%

and 100%, respectively.
It has a Good repeatability.
It has a good inter-assay precision and intra-assay precision.
4. Clinical evaluation
When each test strip is tested individually, the positive coincidence rate is less than 85% or lower; when the antigen,IgM and IgG are tested in combination, the positive coincidence rate and accuracy are both above 95%.
5. Hook effect
Within the concentration of positive specimens of the Typhoid antibody, the test result of this product does not show a hook effect.
6. The minimum detection limit
The minimum detection limit of IgM is 120pg/ml
The minimum detection limit of IgG is 190pg/ml

【Limitations】

1. Read the package insert in its entirety prior to performing the test. Failure to follow the package insert instructions may result in an invalid test result.
2. This product is for qualitative assessment only. This test is only provided for use by clinical laboratories or to health care workers for point of care testing.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. Negative results do not preclude Typhoid infection and should not be used as the sole basis for patient management decisions. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
5. Due to the limitation of detection sensitivity, negative results may be caused by antibody concentrations lower than the analytical sensitivity of the product.
6. This test will only indicate the presence of Typhoid IgM and/or IgG antibodies in the specimen.
7. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
8. Not for screening of donated blood.

【REFERENCES】

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4. Podolsky I, Lee E, Cohen R, Peterson WL. Prevalence of C. pylori in healthy subjects and patients with peptic diseases. Gastroenteroloty 1989: 96: Suppl: A394. abstract.
5. Kist M., Immunology of Helicobacter pylori. In Helicobacter pylori in peptic ulceration and gastritis, edited by Marshall BJ., McCallum RW., and Guerrant RL., 1991, Chapter8, 92-110.

【Symbols】

 Manufacturer

 Date of manufacture

EC REP	Authorised Representative in the European community		Use by
	Caution	LOT	Batch code
	Do not reuse		Keep dry
	Do not use if package is damaged	Σ	Total number of tests
	instructions for use	IVD	in vitro diagnostic
CE	CE mark		Temperature limit

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