（**FOR RESEARCH USE ONLY. DO NOT USE IT IN CLINICAL DIAGNOSIS !**）

Human Mycoplasma Pneumoniae (MP) IgG Lateral Flow Assay Kit

Catalog No: E-HD-C006

20T/40T

This manual must be read attentively and completely before using this product.

If you have any problem, please contact our Technical Service Center for help.

Toll-free: 1-888-852-8623 Tel: 1-832-243-6086 Fax: 1-832-243-6017
Email: techsupport@elabscience.com
Website: www.vetassay-elab.com

Please kindly provide us the lot number (on the outside of the box) of the kit for more efficient service.

Test principle

This kit applies the capture-GICA (Gold Immunochromatography) method as its principle. The detection zone of nitrocellulose membrane was coated with anti-human IgG antibody, and the control zone was coated with Mycoplasma Pneumoniae (MP) polyclonal antibody. The nitrocellulous (NC) membrane was pre-coated with gold-labeled Mycoplasma Pneumoniae (MP) antigen to be used as the gold pad. If there is a certain concentration of MP-IgG in sample, it will combine with gold-labeled MP antigen and form a gold-labeled "MP antigen-MP IgG" complex. The complex will then move along the detection card and react with the anti-human IgG antibody on the detection line (T-line). Gold-labeled "MP antigen-MP IgG-anti human IgG" complex will accumulate on the detection area and indicates a red line. If there is little or no MP IgG exists, red line will not appear in the detection area.

Kit components

Item	Specification
Detection Card	20T/40T
Sample Diluent	1 vial
Manual	1 copy

Note: All reagent bottle caps must be tightened to prevent evaporation and microbial pollution.

Notes

1. Please read the manual carefully before use, changes of operation may result in unreliable results.
2. Do not use product out of date or in a broken aluminum foil, it is disposable and cannot be used repeatedly.
3. The detection card should be brought to room temperature before opening after take it out from the refrigerator. The opening detection card should be used as soon as possible.
4. Please do not use but not limited to the following liquids for negative control: water, PBS.
5. The tested sample should be fresh and clear. Avoid of using samples of turbidity, polluted, high hemolysis or abnormal viscous.
6. Avoid of touching the chromatography membrane of the sample well and test well.
7. The waste of experiment should be considered as contaminant, and must be properly handled according to the local regulations.
8. Each reagent is optimized for use in the E-HD-C006. Do not substitute reagents from any other manufacturer into the test kit. Do not combine reagents from other E-HD-C006 with different lot numbers.

Storage and expiry date

Storage: Store at 4-30℃. With cool and dry environment.

Expiry date: expiration date is on the packing box.

Requirements of sample

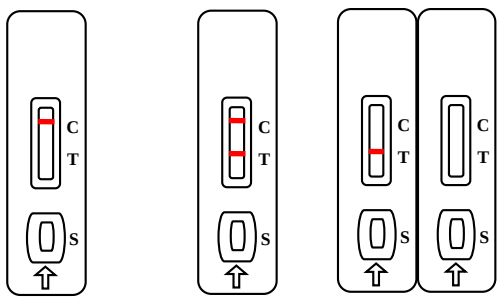
1. The sample must be serum or whole blood.
2. Whole blood samples should be used immediately after collecting, while serum samples can be sto red at 2-8 ℃ temporally for detection, or at -20℃ for long-term storage.
3. Avoid of samples with hemolysis, turbidity, lipidemia, bacterial or polluted and repeated frozen/th awed samples, which will cause false-positive results.

Assay procedure

1. Read the manual carefully before detection. The reagent and sample should be adjusted to room te mperature (15℃ to 30℃) before use. Tear the aluminum foil bag of the detection card and take out the detection card, and put it on a smooth, clean table. Take the detection card out and put it on flat and clean table.
2. Add 10 μL of serum (or 20 μL of whole blood) into the sample well.
3. Observe the result within 15 to 20 min.

Judgment of result

1. **Positive:** red line appears in both test line (T) and control line (C).
2. **Negative:** red line only appears in control line (C).
3. **Invalid:** no color line appears in control line (C). It indicates that the operation is wrong or the detection card is invalid, please carry out another detection.



Negative Positive Invalid

Interpretation of results

1. Positive result indicates there is MP-IgG detected in the sample, and clinical information should be combined with to determine whether the patient have been infected with MP.
2. Negative result indicates there is no MP-IgG detected in the sample, or the concentration is too low to the detection limit. The possibility of MP infection cannot be excluded completely in this situation.

Limitations of this test method

1. This product is for qualitative detection of MP-IgG of serum or whole blood in human, while the detection effect for samples from plasma or other parts is still unclear.
2. The detection results of this kit are only for reference. For confirmation of the result, please combine the symptoms and other methods of detection, this detection cannot be used as the only criteria for result.