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

Human Chlamydia Pneumoniae (CP) IgM Lateral Flow Assay Kit

Catalog No: E-HD-C005

20T/40T

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

If you have any problems, 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-Immunochromatography method as its principle, and can be used for the detection of Chlamydia pneumoniae IgM (CP-IgM) in human serum or whole blood. The quality control (C) line is pre-coated with CP polyclonal antibody, and the detection (T) line is pre-coated with anti-human IgM antibody. The gold pad is coated with gold-labeled CP antigen. CP-IgM in sample will combine with gold-labeled CP antigen and form a gold-labeled antigen-antibody complex. The complex will then move along the detect card and react with the pre-coated anti-human IgM antibody on the detection line (T-line) and form the Anti-human IgM antibody-CP IgM antibody-CP antigen immunological complex, then a visible line will appear in the detection area. If there is no CP IgM antibody or CP IgM antibody content is lower than the detection limit, there will be no complex or precipitation line appeared. The quality control line is standard reference to determine whether the chromatography is normal and whether the detection system is effective. The CP IgM antibody-CP antigen immunological complex and color reaction will occur in the quality control area under all conditions, otherwise the detection result is considered invalid and re-test will be required.

Kit components

Item	Specification
Detect 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 Do not use product out of date or in a broken aluminum foil, it is disposable and cannot be used repeatedly.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-C005. Do not substitute reagents from any other manufacturer into the test kit. Do not combine reagents from other E-HD-C005 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 stored 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/thawed samples, which will cause false-positive results.

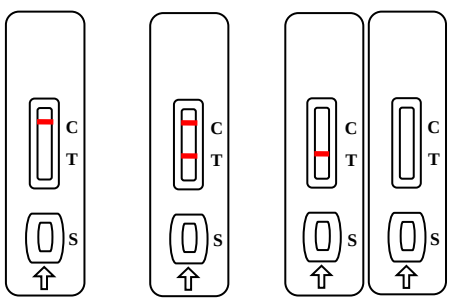
Assay procedure

Read the manual carefully before detection. The reagent and sample should be adjusted to room temperature (15℃ to 30℃) before use. The detect card cannot be opened before the experiment condition is ready.

1. Take out the detection card and put it on a clean table. The detection card must be use in 30 min after opening the aluminum foil.
2. Add 10 μL serum (20 μL whole blood) to the sample well and then add 1 drop (50 μL) of **Sample Diluent**.
3. Incubate for 15 to 20 minutes and then judge the results immediately.

Judgment of result

1. **Positive:** Both the test line region (T) and the control line region (C) show a red line in the observation well.
2. **Negative:** Only the control line region (C) shows a red line in the observation well.
3. **Invalid:** No color line shows in the observation well of the control line region (C).It indicates that the operation is wrong or the detect card is invalid, please carry out another detection.



Negative Positive Invalid

Interpretation of results

1. **Positive result:** The sample contains CP IgM, and clinical information needs to be combined to determine whether the patient has been infected with CP.
2. **Negative result:** No CP IgM was detected in the sample, or the content is too low to the detection limit. The possibility of being infected cannot be completely excluded at this situation.

Limitations of this test method

1. This product is for qualitative detection of CP IgM in serum or whole blood, while the detection effect for plasma samples or samples from 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.