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

Human Cytomegalo Virus (CMV) IgG Lateral Flow Assay Kit

Catalog No: E-HD-C031

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 Indirect-GICA (Gold Immunochromatography) method as its principle, and can be used for the qualitative detection of Cytomegalo Virus (CMV) IgG in human serum. The quality control (C) line is pre-coated with Protein-A antibody, and the detection (T) line is pre-coated with genetic recombinant CMV antigen. The gold pad is coated with gold-labeled Protein-A. CMV IgG in sample will combine with gold-labeled Protein-A and form a gold-labeled Protein-A-CMV IgG antibody complex. The complex will then move along the detection card and react with the pre-coated CMV antigen on the detection line (T-line) and form the CMV antigen-CMV IgG antibody-gold-labeled Protein-A immunological complex, then a visible line will appear in the detection area. If there is no CMV IgG antibody or CMV IgG 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 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
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 Do not use product out of date or in a broken aluminum foil, it is disposable and cannot be used repeatedly.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-C031. Do not substitute reagents from any other manufacturer into the test kit. Do not combine reagents from other E-HD-C031 with different lot numbers.

Storage and expiry date

Store the kit at 4-30℃. Do not freeze any test kit components.

Expiry date: expiration date is on the packing box.

Requirements of sample

1. **Serum:** Human serum can be used as detected sample. Prepared serum samples can be stored at 2-8℃ temporally for detection, or at -20℃ for long-term storage.
2. Avoid of samples with hemolysis, turbidity, lipidemia, bacterial or polluted and repeated frozen/thawed samples, which will cause false-positive results.
3. Hemolysis samples with ≥ 450 mg/mL hemoglobin, jaundice sample with ≥ 1.6 mmol/L bilirubin, high fat sample with ≥ 160 mmol/L glycerin trilaurate and serum sample with ≥ 500 mg/dL cholesterol will interfere the detection of CMV IgG antibody with this kit.

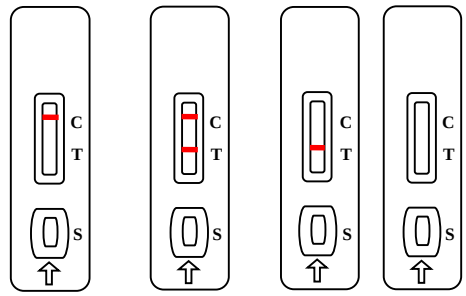
Assay procedure

Allow all kit components and sample to reach room temperature (25 ℃) prior to testing.

1. Tear the aluminum foil bag of the detection card and take out the detection card, and put it on a smooth, clean table.
2. Add 10 μL of serum to the sample well and then add 2-3 drops (or 90 μL) of sample diluent.
3. Incubate for 10 to 20 minutes and then judge the results immediately.

Judgment of result

1. **Negative:** Only the control line region (C) shows a line in the observation well.
2. **Positive:** Both the test line region (T) and the control line region (C) show a 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 detection card is invalid, please carry out another detection.



Negative Positive Invalid

Interpretation of results

1. **Positive result:** The sample contains CMV IgG antibody.
2. **Negative result:** No CMV IgG 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

This product is for qualitative detection of CMV IgG in serum only, while the detection effect for whole blood samples, plasma samples or samples from other parts is still unclear.