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

**Human Cytomegalovirus, Toxoplasma, Rubella, Herpes simplex virus type II IgM
Lateral Flow Assay Kit**

Catalog No: E-HD-C002

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 is composed of nitrocellulose membrane pre-coated with genetic recombinant antigen of CMV, TOX, RV and HSV- II and other reagents. It applies the Capture-GICA (Gold Immunochromatography) method as its principle, and can be used for the qualitative detection of TORVH (TOX, RV, CMV, HSV- II) IgM in human serum.

Each one detection card constitutes an independent detection unit, which contains four detection card for CMV IgM, TOX IgM, RV IgM and HSV- II IgM respectively. Cellulose film is pre-coated with anti-human IgM antibody. The gold pad is coated with gold-labeled CMV, TOX, RV and HSV- II antigen. The gold pad is pre-coated with gold-labeled genetic recombinant antigen of CMV, TOX, RV and HSV- II.

Kit components

Item	Specification
Detection Card (with pipette)	20T/40T
Sample Diluent	1 vial
Manual	1 copy

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 Do not use product out of date or in a broken aluminum foil, it is disposable and cannot be used repeatedly.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-C002. Do not substitute reagents from any other manufacturer into the test kit. Do not combine reagents from other E-HD-C002 with different lot numbers.

Storage and expiry date

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

Expiry date: expiration date is on the box.

Requirements of sample

1. The sample must be serum.
2. Whole blood should be used immediately after collecting, and the prepared serum samples can be stored at 2-8 °C temporarily for detection, or at -20°C 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.

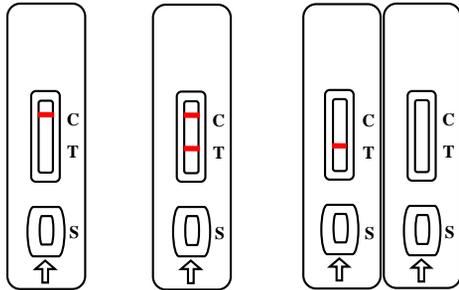
Assay procedure

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

1. Take the detection card out and put it on flat and clean table.
2. Add 10 µL of serum to the sample well and then add 1 drops (or 50 µL) of **Sample Diluent**.
3. Observe the result within 15-20 min. The result is invalid after 20 min.

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 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:** The sample contains CMV, or TOX, or RV and HSV- II IgM antibody, and information needs to be combined to determine whether the patient has been infected with TORCH. The deeper color of detection line indicates the concentration of corresponding IgM antibody is higher.
2. **Negative result:** No CMV, TOX, RV and HSV- II IgM was detected in the sample, indicating that there was no recent infection with giant cells or toxoplasma or rubella virus or herpes simplex virus type II. If you have recently infected a giant cell or toxoplasma or rubella virus or herpes simplex virus type II, but the specimen is sampled too early, a negative result may result. Therefore, negative conclusions are not necessarily correct.
3. When the test results show ambiguous results, it is recommended to retest. If the recurrence test still does not give a definitive result, it should be changed to other serological methods.

Limitations of this test method

This product is for qualitative detection of CMV, TOX, RV and HSV- II IgM in serum only, while the detection effect for whole blood samples, plasma samples or samples from other parts is still unclear.