

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

## **Human Enterovirus 71 (EV71) IgM Lateral Flow Assay Kit**

Catalog No: E-HD-C016

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](mailto:techsupport@elabscience.com)

Website: [www.vetassay-elab.com](http://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, and can be used for the detection of Enterovirus 71 (EV71) IgM in human serum. The quality control (C) line is pre-coated with EV71 antibody, and the detection (T) line is pre-coated with anti-human IgM antibody ( $\mu$ -chain). The gold pad is coated with gold-labeled EV71 monoclonal antibody-EV71 antigen complex. EV71 IgM in sample will combine with gold-labeled EV71 monoclonal antibody-EV71 antigen complex and form a gold-labeled antigen-antibody complex. The complex will then move along the detection card and react with the pre-coated anti-human IgM antibody on the detection line (T-line) and form the “Anti-human IgM antibody-EV71 IgM-gold- labeled EV71 monoclonal antibody-EV71 antigen” immunological complex, then a visible line will appear in the detection area. If there is no EV71 IgM antibody or EV71 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 EV71 antibody- CV-A16 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
Detection Card (with pipette )	20T/40T
Sample Diluent	1 vial
Manual	1 copy

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

**Requirements of sample**

1. The sample must be serum or whole blood samples.
2. Hemolysis samples with  $\geq 500$  mg/mL hemoglobin, jaundice sample with  $\geq 1.8$  mmol/L bilirubin and high fat sample with  $\geq 180$  mmol/L glycerin trilaurate will interfere the detection of HAV IgM antibody with this kit.
3. Separate the serum immediately after collecting, and the prepared serum samples can be stored at 2-8°C for 2 days or at -20°C for a long-term storage..
4. Heat treated samples may interfere the detection result.
5. Don't use hemolysis, turbidity, hyperlipidemic or polluted samples. Avoid repeated freeze-thaw cycles. Otherwise, it will affect the accuracy of the results.

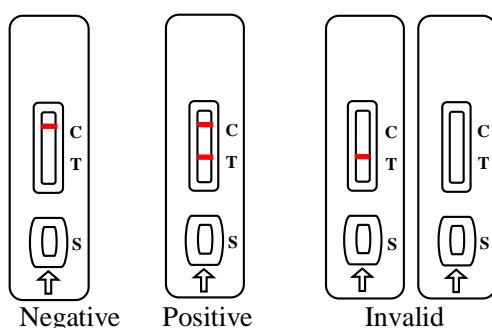
## Assay procedure

Read the manual carefully before detection. Bring detection card and sample to room temperature (30°C) 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  $\mu\text{L}$  of serum or 20  $\mu\text{L}$  of whole blood to the sample well (S) vertically and slowly (make sure that there is no liquid out flowing from the well). and then add 1 drops 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 line in the observation well.
2. **Negative:** Only the control line region (C) shows 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.



## Interpretation of results

1. **Positive result:** The sample contains EV71 IgM antibody. It might be infected with EV71, and the result should be combined with other methods to analyze.
2. **Negative result:** No EV71 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 EV71 IgM in serum or whole blood sample, while the detection effect for plasma samples or samples from other parts is still unclear.
2. **Cross reaction:** This kit has no cross reaction with EV71 IgG, HEV IgG, HAV IgM, HIV IgG, HCV IgG positive sample.

## 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-C016. Do not substitute reagents from any other manufacturer into the test kit. Do not combine reagents from other E-HD-C016 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 packing box.