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

Human Hepatitis E Virus (HEV) IgG Lateral Flow Assay Kit

Catalog No: E-HD-C013

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-GICA (Gold Immunochromatography) method as its principle. The detection zone of nitrocellulose membrane was coated with genetic engineering Hepatitis E Virus (HEV) antigen, and the control zone was coated with rabbit-anti mouse IgG polyclonal antibody. The nitrocellulous (NC) membrane was pre-coated with gold-labeled mouse-anti human HEV-IgG to be used as the gold pad. If there is a certain concentration of HEV-IgG in sample, it will combine with gold-labeled mouse-anti human IgG and form a gold-labeled "mouse-anti human IgG-HEV IgG" complex. The complex will then move along the detection card and react with the HEV antigen on the detection line (T-line). Gold-labeled "HEV antigen-HEV IgG-anti human IgG" complex will accumulate on the detection area and indicates a red line. If there is little or no HEV IgG exists, red line will not appear in the detection area. The quality control area (C line) on the detection card is standard reference to determine whether the chromatography is normal and whether the detection system is effective. The red line should appear under all conditions. Otherwise the detection result is considered invalid and re-test will be required.

Kit components

Item	Specification
Detection card	20/40 T
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 Do not use product out of date or in a broken aluminum foil, it is disposable and cannot be used repeatedly.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. The test environment should be kept at a fixed temperature to avoid testing at high temperatures.
9. Each reagent is optimized for use in the **E-HD-C013**. Do not substitute reagents from any other manufacturer into the test kit. Do not combine reagents from other **E-HD-C013** with different lot numbers.

Storage and expiry date

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

Expiry date: expiration date is on the packing box.

Sample preparation

1. **Serum:** Use the conventional method to prepare serum, the serum must be clear, no hemolysis and no pollution. Samples can be conserved at 2-8℃ in 1 week, and it should be stored at - 20℃ for a long term storage.
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.

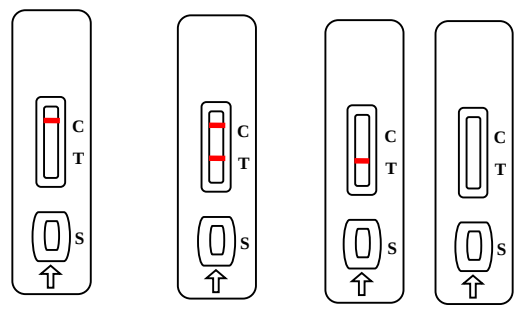
Assay procedure

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 **sample** and 2 drops of **Sample Diluent** to the sample well vertically and slowly (Avoid foaming).
3. Incubate for 15 to 20 minutes and then judge the results immediately.

Judgment of result

1. **Positive:** Red line appears in both test line and control line (C). The shade of the precipitation line is positive proportional to the concentration of detected target in sample.
2. **Negative:** Only the control line region (C) shows a 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 indicates there is HEV-IgG detected in the sample, and clinical information should be combined with to determine whether the patient have been infected with HEV.
2. Negative result indicates there is no HEV-IgG detected in the sample, or the concentration is too low to the detection limit. The possibility of HEV infection cannot be excluded completely in this situation

Limitations of this test method

1. This kit can only be used for qualitative detection of HEV-IgG in serum of human.
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.