7th Edition, revised in April, 2017

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

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

Catalog No: E-HD-C014

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, and can be used for the detection of Hepatitis E Virus (HEV) IgM in human serum. The quality control (C) line is pre-coated with HEV polyclonal antibody, and the detection (T) line is pre-coated with anti-human IgM antibody. The gold pad is coated with gold-labeled HEV antigen. HEV IgM in sample will combine with gold-labeled HEV antigen 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- HEV IgM antibody-HEV antigen immunological complex, then a visible line will appear in the detection area. If there is no HEV IgM antibody or HEV 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 HEV IgM antibody-HEV IgM 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	20T/40T
Sample Diluent	1 vial
Manual	1 copy

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 ℃ 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.

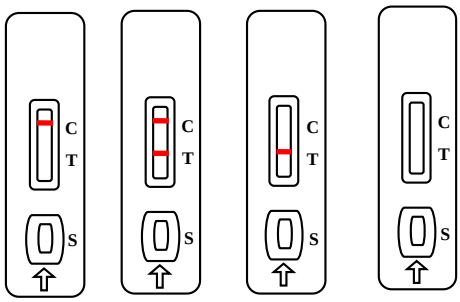
Assay procedure

Read the manual carefully before detection. The reagent and sample should be adjusted to room temperature (15℃ to 30℃) before use. The 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 into the sample well, then add 2 drops (or 100 μL) of sample diluent into to the sample well.
3. Observe the result within 15-20 min. The result is invalid after 20 min.

Judgment of result

1. **Positive:** Red line appears in both test line (T) and control line (C).
2. **Negative:** Red line only appears in control line (C).
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 HEV IgM antibody, and clinical information needs to be combined to determine whether the patient has been infected with HEV.
2. **Negative result:** No HEV IgM I 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 HEV IgM in serum samples only, while the detection effect for whole blood samples, plasma samples or samples from other parts is still unclear.

Product performance index

1. **Coincidence of positive reference:** The detection result of 9 positive references were all positive.
2. **Coincidence of negative reference:** The detection result of 9 negative references were all negative.
3. **The minimum detection limit reference:** L1, L2, L3, L4 should be tested all positive, L5 should be negative.
4. **Precision reference:** Detect 10 precision references, the results are consistent.
5. **Cross reaction:** This kit has no cross reaction with HAV IgM, HCV IgM, HBC IgM, HDV IgM, CMV IgM, EBV IgG.
6. Samples with ≤1000 mg/dL hemoglobin,≤50 mg/dL bilirubin, ≤500 mg/dL glycerin trilaurate and ≤500 mg/dL cholesterol will not interfere the detection of HEV IgM antibody with this kit.
7. This product has no hook effect.

Notes

1. The test temperature should be kept constant. Avoid of operating under high temperature condition.
2. The detection card should be adjusted to room temperature after removed from the refrigerator before opening.
3. The opening detection card should be used as soon as possible so as not to be invalid because of moisture.
4. The result should be read within 20 min.
5. Components from different batches and kinds of kit cannot be mixed. Do not mix reagents with other producers.

Storage and expiry date

Storage: Store at 4-30℃. With dry condition.

Expiry date: expiration date is on the box.