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

# Human Hepatitis A Virus (HAV) IgM Lateral Flow Assay Kit

Catalog No: E-HD-C010

20T/40T

| | |
|---|---|
| **Version Number:** | V1.2 |
| **Replace version:** | V1.1 |
| **Revision Date:** | 2024.03.14 |

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 method as its principle, and can be used for the detection of Hepatitis A Virus (HAV) IgM in human serum. The quality control (C) line is pre-coated with HAV antibody, and the detection (T) line is pre-coated with anti-human IgM antibody. The gold pad is coated with gold-labeled HAV antigen. HAV IgM in sample will combine with gold-labeled HAV 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-HAV IgM antibody-HAV antigen immunological complex, then a visible line will appear in the detection area. If there is no HAV antibody or HAV 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 HAV IgM antibody-HAV 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 disposable dropper) | 20T/40T |
| Sample Diluent | 20/40 vials |
| 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 Do not use product out of date or in a broken aluminum foil, it is disposable and cannot be used repeatedly.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-C010. Do not substitute reagents from any other manufacturer into the test kit. Do not combine reagents from other E-HD-C010 with different lot numbers.

## Storage and expiry date

**Storage:** Store at 4-30℃. With cool and dry environment.

**Expiry date:** expiration date is on the packing box.

## Requirements of sample

1. The sample must be serum.
2. Hemolysis samples with ≥ 500 mg/mL hemoglobin, jaundice sample with ≥ 1.8 mmol/L bilirubin and high fat sample with ≥ 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℃ for 2 days or at -20℃ 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.

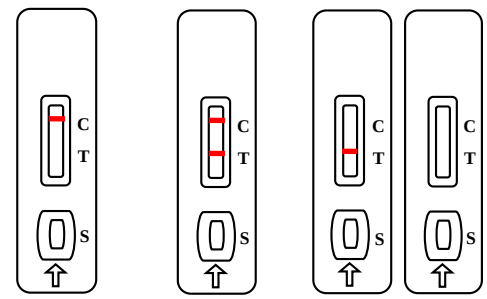
## Assay procedure

Read the manual carefully before detection. Bring detection card and sample to room temperature (30℃) before use. The detect card cannot be opened before the experiment condition is ready.

1. Tear the aluminum foil bag of the detection card and take out the detection card, and put it on a smooth, clean table. (The detection card must be use in 1 h after opening the aluminum foil.)
2. Add 5 μL of serum to the **Sample Diluent** vial**,** mix fully.
3. Add 100 μL of prepared mixed sample solution to the sample well (S) vertically and slowly (make sure that there is no liquid out flowing from the well).
4. 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.




Negative Positive Invalid

## Interpretation of results

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