Hepatitis A Virus (HAV) IgG Rapid Test Kit
Catalog No: E-HD-C023
25T/100T

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.

Phone: 240-252-7368(USA) 240-252-7376(USA)
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Please kindly provide us the lot number (on the outside of the box) of the kit for more efficient service.
**Test principle**

This detection card applies the Indirect-GICA (Gold Immunochromatography) method as its principle. The detection zone of nitrocellulose membrane was coated with mouse-anti-human IgG monoclonal antibody, and the glass fiber paper was pre-coated with gold-labeled natural HAV antigen. Sample will carry out upward chromatography by capillary effect after being added into the sample well of detection card or strip. If there is a certain concentration of HAV IgG antibody in sample, the antibody will combine with gold-labeled natural HAV antigen on the detection card and form a gold-labeled antigen-antibody complex. The complex will then move along the detection card and react with the mouse-anti-human IgG monoclonal antibody on the detection line (T-line). Gold-labeled antigen-antibody-second antibody complex will accumulate in the detection area and indicates a red line. If there is little or no HAV IgG antibody 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 condition. Otherwise the detection result is considered invalid and re-test will be required.

**Kit components**

<table>
<thead>
<tr>
<th>Item</th>
<th>Specification</th>
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<tbody>
<tr>
<td>Detection card</td>
<td>25</td>
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<tr>
<td>Sample diluent</td>
<td>25 vials</td>
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<tr>
<td>Manual</td>
<td>1 copy</td>
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</tbody>
</table>

**Requirements of sample**

1. Human serum/plasma or whole blood can be used as test sample. Anticoagulants (heparin, EDTA, sodium citrate) has no interference to the test results.
2. Serum/plasma samples can be kept stable for 3 days at 2–8℃, it is recommended to be used within 72 hours. Whole blood sample should be used immediately after collecting. Serum/plasma samples can be kept stable for 1 year when stored at -20℃ immediately for long-term storage. It is suggested that the freeze-thaw cycles should be no more than 3 times for serum/plasma samples.
3. Avoid using samples with hemolysis or lipidemia. Polluted samples can't be detected.

**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 5 μL of sample to the sample well and then add 2–3 drops (100~150 μL) of sample diluent.
3. Observe the result within 20 min. The result is invalid after 30 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.

Interpretation of results

1. **Positive result**: The sample has been infected with HAV or inoculated with HAV vaccine and the titer of produced antibody was not less than 20 mIU/mL.
2. **Negative result**: The sample has not been infected with HAV or inoculated with HAV vaccine, or the sample inoculated with HAV but the titer of produced antibody was less than 20 mIU/mL.
3. **Suspicious result**: It is recommended to do repeat detection or re-test after two weeks, and dynamically observe the change in antibody level.

Limitations of this test method

1. This product is for qualitative detection only, used as auxiliary diagnosis. The specific content of antibody in sample cannot be determined. The analysis of detection result should be combined with clinical symptoms.
2. The individual differences or operation procedures may affect the result.
3. Hemolysis, lipid and jaundice may affect the judgment of the detection result.
**Product performance index**

1. **Coincidence of positive reference:** The detection result of 10 positive references were all positive.
2. **Coincidence of negative reference:** The detection result of 10 negative references were all negative.
3. **Sensitivity:** The detection result of sensitivity reference meet the required standard.
4. **Precision:** Detect 10 precision references, the results are consistent.
5. **Anti-interference performance:** Samples with hemolysis and blood lipid may have interference for the results, it should be avoided. Samples with auto-antibodies (rheumatoid factor, anti-nuclear antibody) will not interfere this product.
6. **Cross reaction:** This kit has no cross reaction with positive samples of Hepatitis B virus surface antibody, Hepatitis C virus IgG antibody, Schaudinn's bacillus IgG antibody, HIV virus IgG antibody, Cytomegalovirus IgG antibody, Herpes simplex virus IgG antibody. This product has not been used with non-specific high IgG, non-specific high IgA and HAMA sample, thus clinical use should be avoided.

**Notes**

1. Instructions should be followed strictly.
2. This product should be stored at 2~30°C. Prevent from freezing. The valid period is 18 months. The reagents that exceed the validity date may not be used.
3. All samples and waste material should be treated as infective material.
4. The excess of whole blood sample may lead to slow chromatography, chromatography failure and the accumulation of red blood cells in the detection area which will affect the observation of result.
5. The detection card should be used within 1 hour after taken out. Especially under high temperature condition the detection operation should be finished as soon as possible.
6. This product is disposable and cannot be used repeatedly.
7. This product is for research use only.

**Storage and valid period**

**Storage:** Store at 2-30°C with dry condition.

**Valid Period:** 1 year, production date is on the packing box.