Instructions for Use

Version: 1.0.2

Revision date: 3-Aug-23



Hepatitis A Virus IgG and IgM (HAV IgG + IgM) Rapid Test Kit

Catalog No.: abx092201

Size: 20 tests

Storage: Store all reagents at 2-30°C. Keep dry.

Application: For qualitative detection of Hepatitis A Virus IgG and IgM in Human serum, plasma or whole blood.

Introduction and assay principle

Abbexa's Hepatitis A Virus IgG and IgM Rapid Test Kit is based on the gold immuno-chromatography assay (GICA) principle. Any Hepatitis A Virus IgG and IgM present in the samples binds with colloidal gold particle-labelled Hepatitis A Virus antigen antibody. Anti-IgG and Anti-IgM antibodies are coated on the test lines G and M respectively. When the concentration of Hepatitis A Virus IgG or IgM in the sample is more than the detection limit, there is a color change in the respective detection line and the result is positive. When the concentration of Hepatitis A Virus IgG and IgM in the sample solution is less than the detection limit, there is no color change in the respective detection line and the result is negative.

Kit Components

Test cassettes: 20

Sample diluent

Material Required But Not Provided

- High-precision pipette and sterile pipette tips
- Timer

Sample preparation

- **Serum:** Samples should be collected into a serum separator tube. Coagulate the serum by leaving the tube undisturbed in a vertical position overnight at 4°C or at room temperature for up to 1 hr. Centrifuge at approximately 1000 × g for 20 mins. If precipitate appears, centrifuge again. Assay immediately or aliquot and store between 2-8 °C for short-term storage (up to 5 days) or -20 °C for long-term storage.
- Plasma: Collect plasma using EDTA, citrate or heparin as an anticoagulant. Centrifuge for 15 mins at 1000 × g, within 30 mins of collection. If precipitate appears, centrifuge again. Avoid hemolytic samples. Assay immediately or aliquot and store between 2-8 °C for short-term storage (up to 5 days) or -20 °C for long-term storage.
- Whole blood (venipuncture): Collect whole blood using EDTA, citrate or heparin as an anticoagulant. Assay immediately or store between 2-8°C for up to 24 hours. Do not freeze whole blood samples.
- Whole blood (fingerstick): Wash hands thoroughly with soap and water. Ensure fingertips are clean and dry. Using a lancet, press against the fingertip to puncture. Use a clean paper towel or similar material to wipe off the first drop of blood. Gently massage the finger from knuckle to fingertip to allow a second drop of blood to form. Immediately collect 1 drop (approximately 40-50 µl) of blood and assay immediately.

Assay procedure

Bring all kit components and samples to room temperature prior to assay. The test cassette should be used within 1 hour after removing from the sealed pouch.

- 1. Take a test cassette and lay it flat on a clean table. Accurately add 5 µl of serum, plasma or whole blood sample to the sample well (S) on the test cassette. Slowly and vertically add 3 drops (approximately 80-100 µl) of sample diluent to the Buffer well (B). Avoid foaming.
- 2. Leave at room temperature for 15 min, then analyze the result. Results must be read within 30 minutes.

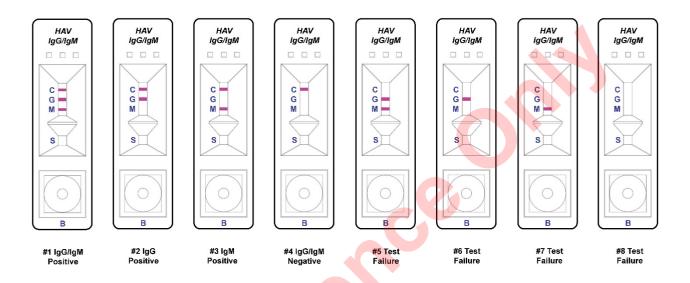
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Results analysis

- IgG Positive result: A colored line is observed in both the control (C) section and the IgG (G) section.
- IgM Positive result: A colored line is observed in both the control (C) section and the IgM (M) section.
- IgG Negative result: A colored line is observed in both the control (C) section and not the IgG (G) section.
- IgM Negative result: A colored line is observed in both the control (C) section and not the IgM (M) section.
- Invalid result: No colored line is observed in the control (C) section.



Notes

- 1. The test cassettes should be brought to room temperature before use.
- 2. After opening the aluminum foil, use the test cassette as soon as possible.
- 3. Samples should be clear with no visible particles, turbidity or bacterial pollution.
- 4. Do not mix or re-use the pipettes to avoid cross-contamination.
- 5. Do not use water, PBS, or similar solutions as the negative control.
- 6. Avoid touching the cassette membrane through the sample well or test result window.
- 7. This kit is for qualitative detection of Hepatitis A Virus IgG and IgM in serum, plasma or whole blood samples. For other sample types, a preliminary experiment is recommended to determine compatibility with this kit. Positive samples can be tested with another method (e.g. HPLC, LC/MS) for quantitative results.
- 8. This kit is for research use only and the results are for reference only.
- 9. It is recommended to use this kit in conjunction with another detection method.
- 10. All waste should be disposed appropriately. Please note that you may need to follow special waste disposal procedures for infectious samples. Please check local disposal regulations.
- 11. No false positives were observed with the following pathologies: HBV, HCV, HEV, HIV, hCG, Dengue, H. pylori, Malaria, TB, T. pallidum, Typhoid, ANA, HAMA, and RF (up to 1,000 IU/ml).