

1. INTENDED USE

The Biokits HAV IgM Rapid Test is an in-vitro diagnostic, immunochromatographic assay for the qualitative detection of IgM antibodies to Hepatitis A Virus (HAV) in human whole blood, serum, or plasma. This test is intended for professional use only.

2. INTRODUCTION

Hepatitis A virus (HAV) is an acute viral infection of the liver transmitted primarily through the fecal–oral route. Detection of anti-HAV IgM antibodies indicates acute or recent HAV infection and is essential for early diagnosis and patient management. Anti-HAV IgM antibodies appear early during infection and generally persist for several months. The Biokits HAV IgM Rapid Test provides a rapid qualitative result to assist in the diagnosis of acute Hepatitis A infection.

3. PRINCIPLE OF THE TEST

The Biokits HAV IgM Rapid Test is a lateral-flow immunochromatographic assay with a two-line detection system consisting of a test line (T) and a control line (C). Anti-HAV IgM antibodies present in the specimen bind to colloidal gold-conjugated HAV antigens and migrate along the membrane by capillary action. The immune complexes are captured by immobilized anti-human IgM antibodies at the test line region, producing a visible colored line when anti-HAV IgM is present. The control line is coated with polyclonal antibodies and reacts with a colored control conjugate, producing a visible line independent of the presence of HAV IgM, thereby confirming proper sample flow, reagent integrity, and test validity.

4. KIT COMPONENTS

Each kit contains:

1. Individually pouched HAV IgM Test Devices with desiccant
2. Assay Diluent / Buffer vial(s)
3. Instructions for Use (IFU)

5. KIT STORAGE AND STABILITY

1. Store at 2–30°C. Do not freeze.
2. Protect from direct sunlight and humidity.
3. Use the device immediately after opening the foil pouch.
4. Do not use if the pouch is damaged or the seal is broken.
5. Do not mix components from different lots.
6. Use before the expiry date printed on the packaging.

6. PRECAUTIONS

1. For In-Vitro Diagnostic Use Only.
2. Do not reuse the test device.
3. Avoid testing hemolytic, lipemic, or icteric specimens.
4. Use separate droppers or pipette tips for each specimen to prevent cross-contamination.
5. Wear gloves and adhere to standard laboratory biosafety practices.
6. Do not eat, drink, or smoke in the testing area.
7. Dispose of all used materials as per biomedical waste regulations.
8. Ensure all reagents and specimens are at room temperature before testing.

7. LIMITATIONS

1. This test is qualitative and does not provide an antibody titer.
2. A negative result does not exclude HAV infection, particularly during the early window period.
3. False-positive results may occur due to non-specific IgM responses.
4. Clinical decisions should not be based solely on this test; additional clinical and laboratory evaluations are required.
5. The test is validated only for human whole blood, serum, or plasma.

8. SAFETY INFORMATION

1. Handle all specimens as potentially infectious.
2. Use appropriate PPE such as gloves, lab coat, and eye protection.
3. Clean spills thoroughly with suitable disinfectants.
4. Dispose of used test components according to biomedical waste disposal guidelines.
5. Do not pipette by mouth.

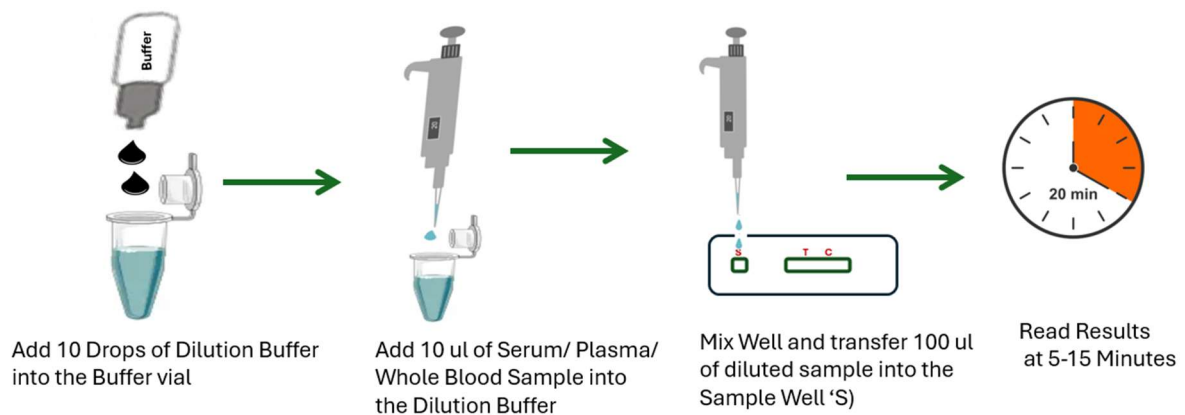
9. REFERENCES

1. Lemon SM, Ott JJ, Van Damme P, Shouval D. *Type A viral hepatitis: a summary and update on the molecular virology, epidemiology, pathogenesis, and prevention.* Journal of Hepatology. 2018;68(1):167–184.

SPECIMEN COLLECTION AND STORAGE

Category	Details
Accepted Specimens	<ul style="list-style-type: none"> ✓ Whole blood (finger prick or venous) ✓ Serum ✓ Plasma (EDTA, citrate, heparin)
Collection	<ul style="list-style-type: none"> ✓ Finger prick or venous blood using standard procedures ✓ For serum: allow to clot, then centrifuge For plasma: centrifuge anticoagulated blood
Storage	<ul style="list-style-type: none"> ✓ Test as early as possible ✓ Store at 2–8°C for up to 3 days ✓ For longer storage, freeze serum/plasma at –20°C Avoid freeze–thaw cycles

TEST PROCEDURE



Note: Do not read results after 15 min- it may give incorrect results !

RESULT INTERPRETATION

