Cat: BHCV-01

BioKits HCV Rapid Test

(Serum-Plasma-Whole Blood)

BioKits DIAGNOSTICS SOLUTIONS

1. INTENDED USE

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

2. INTRODUCTION

Hepatitis C virus (HCV) is a blood-borne viral pathogen that primarily affects the liver and can lead to chronic hepatitis, cirrhosis, and hepatocellular carcinoma. Many HCV infections remain asymptomatic for prolonged periods, making early detection essential for disease control and treatment initiation. Detection of anti-HCV antibodies is widely used as a screening tool for HCV infection. The Biokits HCV Rapid Test provides a rapid qualitative result to assist in the screening and diagnosis of HCV infection.

3. PRINCIPLE OF THE TEST

The Biokits HCV 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-HCV antibodies present in the specimen bind to colloidal gold-conjugated recombinant HCV antigens and migrate along the nitrocellulose membrane by capillary action. The immune complexes are captured by immobilized HCV antigens at the test line region, producing a visible colored line when anti-HCV antibodies are 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 anti-HCV antibodies, thereby confirming proper sample flow, reagent integrity, and test validity.

4. KIT COMPONENTS

Each kit contains:

1. Individually pouched HCV Test Devices with desiccant
2. Assay Diluent / Buffer vial(s)
3. Sample Dropper
4. 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 concentration.
2. A negative result does not exclude HCV infection, particularly during the early window period.
3. False-positive results may occur due to cross-reactive antibodies or non-specific binding.
4. Clinical decisions should not be based solely on this test; results should be interpreted in conjunction with clinical findings and other laboratory investigations.
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.

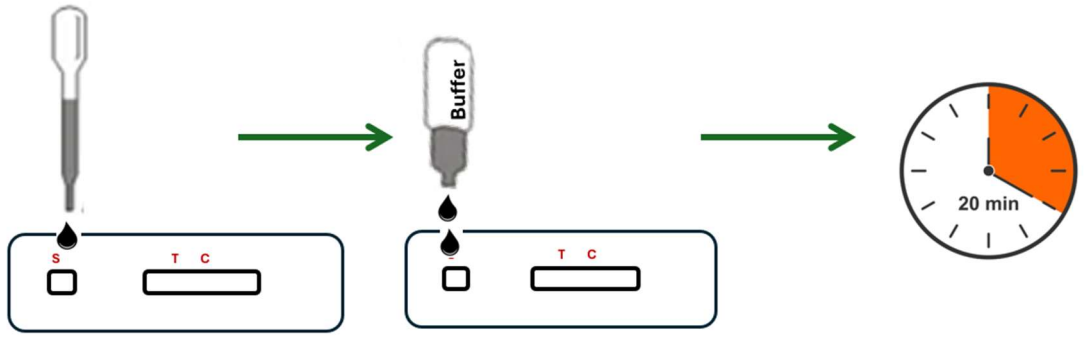
9. REFERENCES

World Health Organization. *Guidelines for the screening, care and treatment of persons with chronic hepatitis C infection.* WHO Press, Geneva.

SPECIMEN COLLECTION AND STORAGE

Category	Details
Accepted Specimens	✓ Whole blood (finger prick or venous) ✓ Serum ✓ Plasma (EDTA, citrate, heparin)
Collection	✓ Finger prick or venous blood using standard procedures ✓ For serum: allow to clot, then centrifuge For plasma: centrifuge anticoagulated blood
Storage	✓ 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



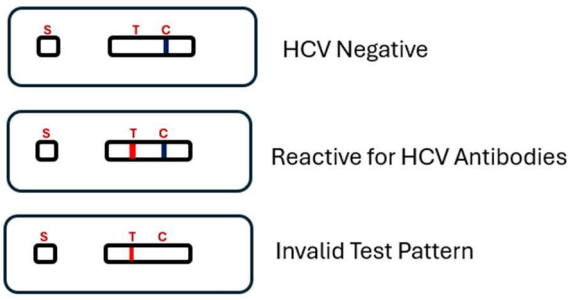
Add 1 Drops (25 ul) of Serum/Plasma/whole blood into the Sample Well "S"

Add 2 Drops (60 ul) of Assay Buffer into the Sample Well "S"

Read Results at 5-20 Minutes

Note: Do not read results after 20 min- it may give incorrect results !

RESULT INTERPRETATION



PERFORMANCE CHARACTERISTICS

- ✓ Clinical Sensitivity: 100%
- ✓ Clinical Specificity: 99.4%

M/s: **ubio Biotechnology Systems Pvt Ltd. Plot No: 15A, Biotechnology Zone, KINFRA Hitech Park, Kalamaserry, Cochin, Kerala - 683503, INDIA.**

Symbols Used Instructions to use | Do Not reuse | Storage temperature | Away from direct sunlight | Store dry | No of tests | IVD For *In-Vitro* diagnostic use | REF Product code | Manufactured site | Manufactured date | Use before | LOT Lot number