

## 1. INTENDED USE

The Biokits HIV 1/2 Rapid Test is an in-vitro diagnostic, immunochromatographic assay for the qualitative detection of antibodies to Human Immunodeficiency Virus type 1 and type 2 (HIV-1/2) in human whole blood, serum, or plasma. This test is intended for professional use only.

## 2. INTRODUCTION

Human Immunodeficiency Virus (HIV) is the causative agent of Acquired Immunodeficiency Syndrome (AIDS) and is transmitted through blood and certain body fluids. Early detection of HIV infection is critical for timely clinical intervention, counseling, and prevention of transmission. Detection of antibodies to HIV-1 and HIV-2 is widely used for screening and diagnosis of HIV infection. The Biokits HIV 1/2 Rapid Test provides a rapid qualitative result to assist in the screening of HIV infection.

## 3. PRINCIPLE OF THE TEST

The Biokits HIV 1/2 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). Antibodies to HIV-1 and/or HIV-2 present in the specimen bind to colloidal gold-conjugated recombinant HIV antigens and migrate along the nitrocellulose membrane by capillary action. The immune complexes are captured by immobilized recombinant HIV antigens at the test line region, producing a visible colored line when HIV-1 and/or HIV-2 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 HIV antibodies, thereby confirming proper sample flow, reagent integrity, and test validity.

## 4. KIT COMPONENTS

Each kit contains:

1. Individually pouched HIV 1/2 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 determine antibody concentration.
2. A negative result does not exclude HIV infection, particularly during the window period.
3. Positive results should be confirmed using an alternative approved method.
4. Clinical decisions should not be based solely on this test; results must be interpreted in conjunction with clinical findings and other laboratory tests.
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

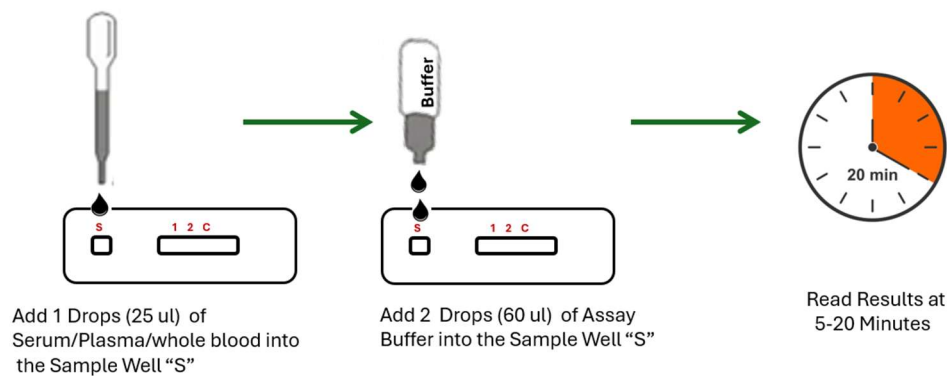
World Health Organization. *Consolidated guidelines on HIV testing services*. WHO Press, Geneva.

## 6. PRECAUTIONS

# SPECIMEN COLLECTION AND STORAGE

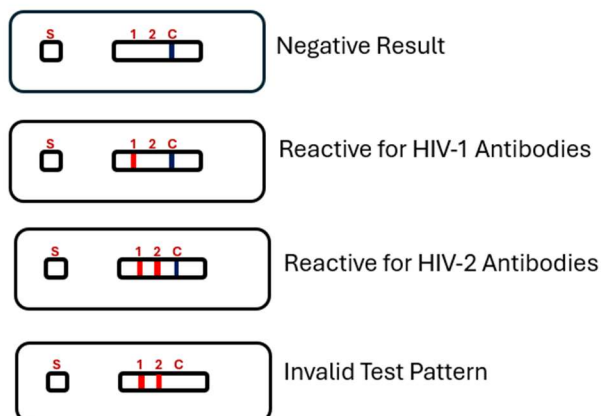
Category	Details
Accepted Specimens	<ul style="list-style-type: none"> <li>✓ Whole blood (finger prick or venous)</li> <li>✓ Serum</li> <li>✓ Plasma (EDTA, citrate, heparin)</li> </ul>
Collection	<ul style="list-style-type: none"> <li>✓ Finger prick or venous blood using standard procedures</li> <li>✓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

## TEST PROCEDURE



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

## RESULT INTERPRETATION



## PERFORMANCE CHARACTERISTICS

- ✓ Clinical Sensitivity: 100%
- ✓ Clinical Specificity: 99.6%