HIV 1/2 Antibody Rapid Test Kit

INTENDED USE

The HIV 1/2 Antibody Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies to Human Immunodeficiency Virus Type 1 and Type 2 in blood serum or plasma to aid in the diagnosis of HIV-1 and HIV-2.

INTRODUCTION

The Human Immunodeficiency Virus (HIV), discovered in 1983, is responsible for the Acquired Immunodeficiency Syndrome and AIDS-related complex. HIV Type 1 and HIV Type 2 are enveloped retroviruses that impact the immune system by depleting the T-helper cells, which make the individual susceptible to infections and some forms of cancer. The means of transmission for these viruses include sex, infected blood, and from parents to offspring.
Detection of antibodies against HIV-1 and HIV-2 in blood, serum, or plasma is crucial for the diagnosis of the disease. There are a variety of HIV detection methods in use today, ranging from Enzyme Immunoassays (EIAs) and Western Blots (WBs) to Nucleic Acid Amplification Tests (NATs) and even point-of-care rapid tests like the HIV 1/2 Rapid Test, which has been designed to accurately reflect clinical realities.

PRINCIPLE

The HIV 1/2 Antibody Rapid Test Kit is an immunoassay based on the principle of the double antigen-sandwich technique. During testing, a specimen migrates upward by capillary action. The antibodies to HIV-1 or HIV-2 if present in the specimen will bind to the HIV conjugates. The immune complex is then captured on the membrane by the pre-coated recombinant HIV antigens, and a visible colored line will show up in the test line region (T1/T2) indicating a positive result. In the absence of antibodies to HIV-1 or HIV-2, a colored line will not form in the test line region indicating a negative result.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS SUPPLIED

Each pack contains: One test device, one disposable dropper, and Silica gel pouch.

STORAGE AND STABILITY

Storage: Store in temperature 2℃ to 30℃. Open the pouch just before use.

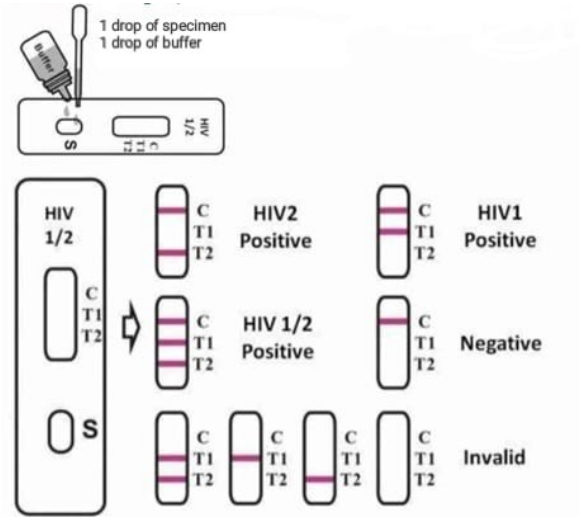
SPECIMEN COLLECTION AND PREPARATION

1. Collect Whole Blood / Serum / Plasma specimens following regular clinical laboratory procedures.
2. Storage: A specimen should be refrigerated if not used on the same day of collection. Specimens should be frozen if not used within 3 days of collecting. Avoid freezing and thawing the specimens more than 2-3 times before using.

ASSAY PROCEDURE

1. Using the enclosed plastic dropper for the sample, dispense 1 drop (35µl) of specimen to the circular sample well of the test card
2. Add 1 drop of Sample Diluent(buffer) to the sample well, immediately after the specimen is added from the dropper tip

diluent vial (or all contents from the single test ampule). Interpret test results within 15 minutes



Notes:

1. Applying a sufficient amount of sample diluent is essential for a valid test result. If migration (the wetting of membrane) is not observed in the test window after one minute, add one more drop of diluent to the sample well.
2. Do not interpret results after 20 minutes

TESTING PROCEDURE AND INTERPRETATION OF RESULTS

RESULT:

1. Positive: Two or three colored lines appear. One line should always appear in the control line region(C), and another one or two apparent colored line(s) should appear in the test line region(s) (T1 and/or T2).
2. Negative: One colored line appears in the control region(C). No apparent colored lines appear in the test line regions (T1 and T2).
3. Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test kit. If the problem persists, discontinue using the batch immediately and contact your local distributor.

LIMITATIONS OF THE TEST

1. Only clear, fresh, free flowing Serum/ Plasma can be used in this test.
2. Fresh samples are best but frozen samples can be used. If a sample has been frozen, it should be allowed to thawed and checked for fluidity.
3. Do not agitate the sample. Insert a pipette just below the surface of the sample to collect the Specimen.