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.

Both HIV-1 and HIV-2 viruses can elicit strong immune responses, including the production of anti-virus antibodies. Presence of specific anti HIV-1 and/or HIV-2 virus antibody in Whole Blood/serum/plasma indicates the exposure of an individual to the HIV-1 and/or HIV-2 virus, being of great value for clinical diagnosis.

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 a proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS AND METHODS

1. Individual sealed pouches, each containing:
   a. 1 × Test Kit
   b. 1 × Desiccant Pouch
   c. 1 × Dropper
2. Buffer Tube

STORAGE AND STABILITY

- Keep the test kit between 2 - 30°C in a dry, cool place. Avoid freezing.
- The kit is stable within the expiry date printed on the product label and outer packaging. Do not use later than the specified date.
- The package should be sealed until it is required for use.

SPECIMEN COLLECTION

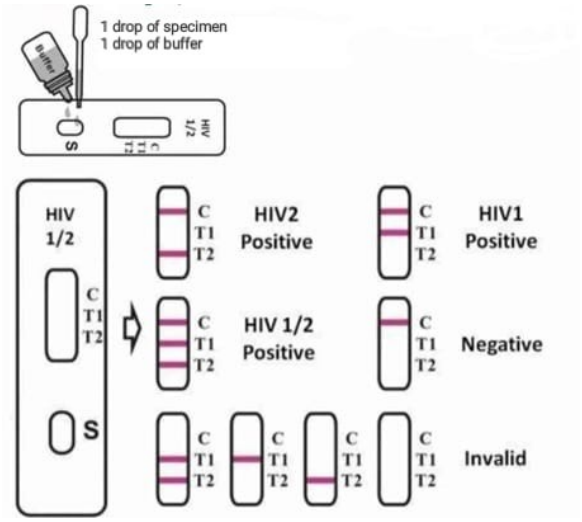
1. The HIV 1/2 Antibody Test can be performed using Whole Blood, Serum or Plasma.
2. Separate the serum or plasma as soon as possible by centrifugation after collecting. Do not leave the specimens at room temperature for prolonged periods.
3. Whole Blood, Serum and plasma specimens may be stored at 2-8 °C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Do not freeze a whole blood specimen. Bring specimens to room temperature prior to testing.
4. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. Do not use samples showing gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

TEST PROCEDURE

Allow the test kit, specimen, and buffer to equilibrate to room temperature (15-30 °C) prior to testing.

1. Remove the test kit from the sealed pouch.
2. Using the enclosed plastic dropper for the sample, dispense 1 drop (35µl) of specimen into the circular sample well of the test card. Add 1 drop of buffer (35µl) to the sample well, immediately after the specimen is added and start the timer.

3. Wait for the colored line to appear. Interpret test results within 15 minutes. Do not read results after 20 minutes.



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.

PERFORMANCE CHARACTERISTICS

A side-by-side comparison was conducted using the HIV 1/2 Antibody Rapid Test and commercially available HIV 1/2 rapid tests. A statistical comparison was made between the results, yielding a clinical sensitivity of 98.7%, a clinical specificity of 99.8% and an accuracy of 99.4%.

LIMITATIONS

1. The HIV 1/2 Antibody Rapid Test Kit(Whole Blood/ Serum/ Plasma) is limited to providing a qualitative detection. The intensity of the test line does not necessarily correlate with the concentration of the antibody in the blood.
2. The results obtained from this test are intended to be an aid in diagnosis only. Each physician must interpret the results in conjunction with the patient's history, physical findings, and other diagnostic procedures.
3. A negative test result indicates that antibodies to HIV 1/2 are either not present or at levels undetectable by the test

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