

One Step HIV (1/2) Rapid Test

For detection of antibodies to HIV1/2 in Human Serum, Plasma or Whole Blood.

IVD In-vitro diagnostic use only



Not reuse

Introduction

The human immunodeficiency virus (HIV) is a retrovirus that infects cells of the immune system, destroying or impairing their function. As the infection progresses, the immune system becomes weaker, and the person becomes more susceptible to infections. The most advanced stage of HIV infection is acquired immunodeficiency syndrome (AIDS). It can take 10-15 years for an HIV-infected person to develop AIDS. The general method of detecting infection with HIV is to observe the presence of antibodies to the virus by an EIA method followed by confirmation with Western Blot. One step HIV(1/2) Test is a simple, visual qualitative test that detects antibodies in human Whole Blood/serum/plasma. The test is based on immunochromatography and can give a result within 15 minutes.

Principle

The HIV 1/2 Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibodies to HIV-1, HIV-2 in whole blood, serum or plasma. The membrane is pre-coated with recombinant HIV antigens in the test line regions, T1 and T2. The T1 test line is pre-coated with HIV-1 antigen and the T2 test line is pre-coated with HIV-2 antigen. During testing, the whole blood, serum or plasma specimen reacts with the mixture of HIV-1 envelope and core antigens and HIV-2 envelope antigen that are coated on colored particles in the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with recombinant HIV antigen on the membrane in the test line region. If the specimen contains antibodies to HIV-1 or HIV-2, one colored line will appear in the test line region; if the specimen contains antibodies to HIV-1 and HIV-2, two colored lines will appear in the test line region. Both indicate a positive result. If the specimen does not contain HIV-1 and/or HIV-2 antibodies, no colored line will appear in the test line region indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

Materials Included and Active Ingredients

- 1) HIV 1/2 kit contains the following items to perform the assay.
 - HIV 1/2 test device foil pouched with a desiccant
 - Instruction for use

Kit Precautions and Storage Instructions

- 1) For best results, adhere to instructions provided
- 2) All specimens should be handled as potentially infectious
- 3) The test device should be stored at room temperature
- 4) The test device is sensitive to humidity as well as heat
- 5) Do not use beyond expiration date
- 6) Do not use test kit if pouch is damaged or seal is broken
- 7) Use test device immediately after removing from the pouch
- 8) The components (test device and assay diluents) in this kit have been quality control tested as a standard batch unit. Do not mix components from different lot numbers.
- 9) Store kit at room temperature (2 -30 °C). Do not expose the kit to temperature over 30 °C

Warnings

- 1) For in vitro diagnostic use only. DO NOT RE-USE test device
- 2) The instructions must be followed to obtain accurate results. Anyone performing an assay with this product must be trained in its use and laboratory procedures.
- 3) Do not eat or smoke while handling specimens
- 4) Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
- 5) Avoid splashing or aerosol formation
- 6) Clean up spills thoroughly using an appropriate disinfectant
- 7) Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
- 8) Do not mix with other specimens.

Specimen Collection, Storage and Precautions

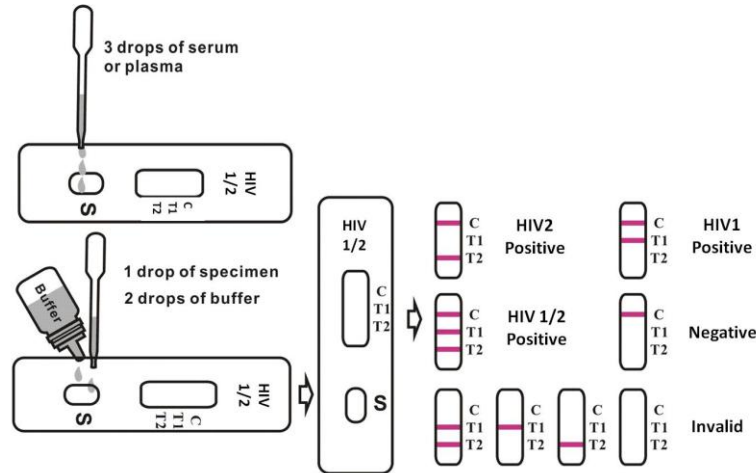
- 1) Serum (S): Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
- 2) Plasma (P): Collect the whole blood into a collection tube (containing anticoagulants such as heparin, EDTA, and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.
- 3) Whole Blood (WB): Collect the whole blood by lancing devices. WB can be delivered by pipette directly to the test card. Preferably, collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture. If blood specimens are not immediately tested, they should be refrigerated at 2~8 °C . When stored at 2~8 °C, the blood specimens should be used within 3 days. For storage period longer than 3 days, freezing is recommended. They should be brought to room temperature (1~30 °C) prior to use. Using the blood specimens in the long-term keeping more than 3 days can cause nonspecific reaction.
- 4) If serum or plasma specimens are not tested immediately, they should be refrigerated at 2-8 °C. For storage periods longer than 2 weeks, freezing is recommended. They should be brought to room temperature (1-30 °C) prior to use.
- 5) Serum or plasma specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.
- 6) Anticoagulants such as heparin, EDTA and sodium citrate do not affect the test results.
- 7) Use separately disposable capillary pipettes or pipette tips for each sample in order to avoid cross-contamination of either samples which could cause erroneous results.
- 8) As known relevant interference, hemolytic samples, rheumatoid factors-contained samples and lipaemic, icteric samples can lead to impair the test results.

Test Procedure (Refer to Figure)

- 1) Allow all test components and specimen to come to room temperature prior to testing
- 2) Remove the test device from the foil pouch, and place it on a flat, dry surface
- 3) For Serum/Plasma specimen, with a micropipette (not provided) or a disposable dropper, add 3 drops about 100 µL of serum/ plasma specimen into the sample well marked "S";
- 4) For Whole Blood specimen, : Hold the dropper vertically and transfer 1 drop of whole blood(approximately 35 µL) to the specimen well(S) of the test device, **Allow about 30 seconds for the specimen to be absorbed totally**. Then add 2 drops of buffer (approximately 70 µl) and start the timer. See illustration below.
- 5) As the test begins to work, you will see red color move across the result window in the center of the test device.
- 6) Interpret test results at 15 minutes. Caution: Do not read test results after 20 minutes. Reading too late can give false results.

Interpretation of Test Results (Refer to Figure)

- Negative:** The control line is the only visible line on the test device. This indicates a negative result.
- Positive:** Two or three distinct 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).
***NOTE:** The intensity of the color in the test line region (T1 and T2) will vary depending on the concentration of HIV antibodies present in the specimen. Therefore, any shade of color in the test line region (T1 and/or T2) should be considered positive
- Invalid:** If the "C" line (control) is not visible within the result window after performing the test, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.



REF RTIV1311-C-1

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Limitations of the Test

- The HIV 1/2 Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of antibodies to HIV in human whole blood, serum or plasma. Neither the quantitative value nor the rate of increase in HIV antibody concentration can be determined by this qualitative test.
- The HIV 1/2 Tri-line Human Immunodeficiency Virus Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of antibodies to HIV in the specimen and should not be used as the sole criteria for the diagnosis of HIV-1 & HIV-2.
- For confirmation, further analysis of the specimens should be performed, such as ELISA and/or Western Blot analysis.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- This test is intended for screening purposes only. Results should not be used to determine the serotype of HIV infections.
- Due to possible cross reactivity, the appearance of lines in both T1 and T2 does not necessarily indicate co-infection from HIV-1 & HIV-2 nor can it identify the serotype.