One Step HIV Ab 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 Ab 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 One Step HIV AbTest is a qualitative membrane strip based immunoassay for the detection of HIV antibodies in Whole Blood /Serum / Plasma. In this test procedure, recombinant HIV antigen is immobilized in the test line region of the device. After a Whole Blood /Serum / Plasma specimen is placed in the specimen well, it reacts with HIV antigen coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized HIV antigen. If the specimen contains HIV antibodies, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain HIV antibodies, a colored line will not appear in this 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 Included and Active Ingredients

1) HIV Ab kit contains the following items to perform the assay.
- HIV Ab test device foil pouched with a desiccant
- Sample diluent
- 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 ^{o}C). Do not expose the kit to temperature over 30 ^{o}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℃ . When stored at 2~8℃, 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℃) 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℃. For storage periods longer than 2 weeks, freezing is recommended. They should be brought to room temperature (1-30℃) 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.

Notes:

Applying sufficient amount of specimen 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 buffer (for whole

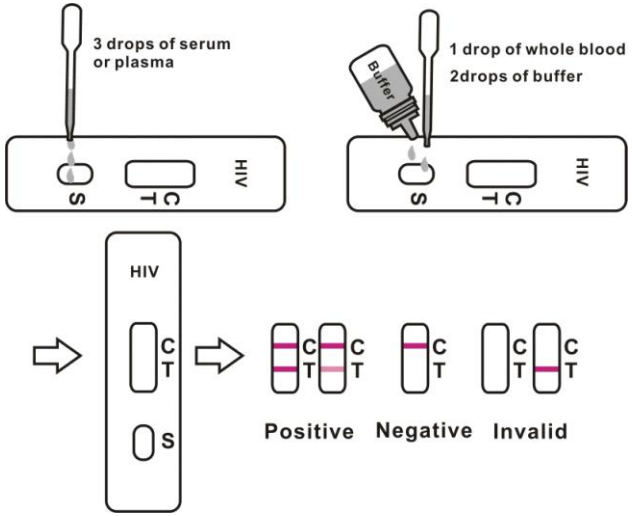
blood) or specimen (for serum or plasma) to the specimen well.

Interpretation of Test Results (Refer to Figure)

1) **Negative:** The control line is the only visible line on the test device. This indicates a negative result.

2) **Positive:** Two lines appear. One line should always appear in the control line region (C), and another one apparent colored line should appear in the test line region
***NOTE:** The intensity of the color in the test line region will vary depending on the concentration of HIV antibodies present in the specimen. Therefore, any shade of color in the test line region should be considered positive

3) **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.



Limitations of the Test

1. The The One Step HIV Ab Test is for in vitro diagnostic use only. The test should be used for the detection of HIV antibodies in Whole Blood /Serum / Plasma specimens only. Neither the quantitative value nor the rate of increase in HIV antibodies can be determined by this qualitative test.
2. The One Step HIV Ab Test will only indicate the presence of HIV antibodies in the specimen and should not be used as the sole criteria for the diagnosis of HIV infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of HIV infection.

REF RTIV21311-C9

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