One Step Syphilis Ab Rapid Test

For detection of Syphilis antibodies in Human Serum, Plasm, Whole Blood

IVD *In-vitro diagnostic use only* *Not reuse*

Introduction

Treponema Pallidum (TP) is the causative agent of the venereal disease syphilis. TP is a spirochete bacterium with an outer envelope and a cytoplasmic membrane. Relatively little is known about the organism in comparison with other bacterial pathogens. According to the Center for Disease Control (CDC), the number of cases of syphilis infection has markedly increased since 1985. Some key factors that have contributed to this rise include the crack cocaine epidemic and the high incidence of prostitution among drug users. One study reported that a large number of HIV-infected females exhibited reactive syphilis serological test results. Multiple clinical stages and long periods of latent, asymptomatic infection are characteristic of syphilis. Primary syphilis infection is defined by the presence of a chancre at the site of inoculation. The antibody response to the TP bacterium can be detected within 4 to 7 days after the chancre appears. The infection remains detectable until the patient receives adequate treatment. The One Step Syphilis Test utilizes a double antigen combination of a syphilis antigen coated particle and syphilis antigen to detect TP antibodies (IgG and IgM) qualitatively and selectively in Whole Blood /Serum / Plasma.

Intended Use

The One Step Syphilis Test is a rapid chromatographic immunoassay for the qualitative detection of antibodies (IgG and IgM) to Treponema Pallidum (TP) in Whole Blood /Serum / Plasma to aid in the diagnosis of syphilis.

Principle

The One Step Syphilis Test is a qualitative membrane strip based immunoassay for the detection of TP antibodies (IgG and IgM) in Whole Blood /Serum / Plasma. In this test procedure, recombinant syphilis 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 syphilis 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 syphilis antigen. If the specimen contains TP antibodies, a colored line will appear in the test line region indicating a positive result. The double antigen test format can detect both IgM and IgG in specimens. If the specimen does not contain TP 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

Materials Provided

- Test devices
- Buffer (for whole blood only)
- Disposable specimen droppers
- Package insert

Materials Required But Not Provided

- Timer
- Specimen collection containers
- Centrifuge

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.

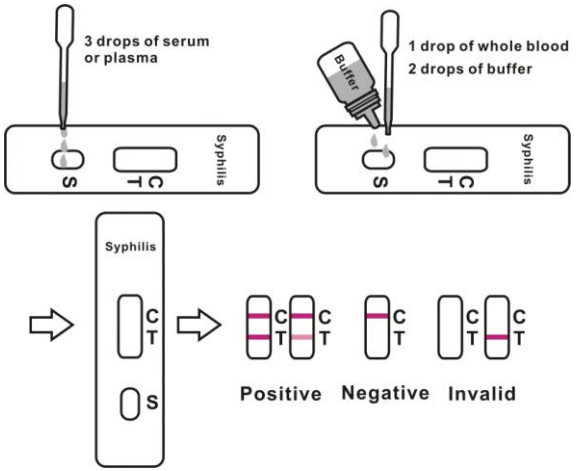
Specimen Collection, Storage and Precautions

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 or plasma specimen: With a micropipette (not provided) or a disposable dropper, add about 100 µL of serum/ plasma specimen into the sample well marked “S”.
4) For whole blood specimens: : 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 15-20 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)

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.

Negative: One colored line appears in the control region(C).No apparent colored line appear in the test line region.

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 with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Limitations of the Test

1. The One Step Syphilis Test is for in vitro diagnostic use only. The test should be used for the detection of TP antibodies in Whole Blood /Serum / Plasma specimens only. Neither the quantitative value nor the rate of increase in TP antibodies can be determined by this qualitative test.
2. The One Step Syphilis Test will only indicate the presence of TP antibodies in the specimen and should not be used as the sole criteria for the diagnosis of Syphilis 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 TP infection.

Internal Quality Control

There is a “Test line” and a “Control line” on the surface of EZ-CARE Syphilis Ab antibodies rapid test cassette. Both the Test Line and Control Line in the result window are not visible before applying any samples. The Control Line is used for procedural control. The Control line should always appear if the test procedure is performed properly and the test reagents of the control line are working. .

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