

One Step Syphilis IgG/IgM Rapid Test

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

IVD In-vitro diagnostic use only



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 IgG/IgM Test is a qualitative membrane strip based immunoassay for the detection of Hepatitis E Virus antibodies (IgG and IgM) in Whole Blood /Serum / Plasma. The test device consists of: 1) a burgundy colored conjugate pad containing SYPHILIS recombinant envelope antigens conjugated with Colloid gold (SYPHILIS conjugates) and rabbit IgG-gold conjugates, 2) a nitrocellulose membrane strip containing two test bands (T1 and T2 bands) and a control band (C band). The T1 band is pre-coated with the antibody for the detection of IgM anti-SYPHILIS, T2 band is coated with antibody for the detection of IgG anti-SYPHILIS, and the C band is pre-coated with goat anti rabbit IgG. When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. IgG anti-SYPHILIS, if present in the specimen, will bind to the SYPHILIS conjugates. The immunocomplex is then captured by the reagent pre-coated on the T2 band, forming a burgundy colored T2 band, indicating a SYPHILIS IgG positive test result and suggesting a recent or repeat infection. IgM anti-SYPHILIS if present in the specimen will bind to the SYPHILIS conjugates. The immunocomplex is then captured by the reagent coated on the T1 band, forming a burgundy colored T1 band, indicating a SYPHILIS IgM positive test result and suggesting a fresh infection. Absence of any T bands (T1 and T2) suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the T bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

Materials Included and Active Ingredients

Materials Provided

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

Materials Required But Not Provided

- Timer
- Centrifuge

- Specimen collection containers

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) With a micropipette (not provided) or a disposable dropper, add about 10 µL of serum/ plasma or whole blood specimen into the sample well marked "S"; **Allow about 30 seconds for the specimen to be absorbed totally.**
- 4) Add 3 drop of diluents buffer to the sample well.
- 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.

Syphilis IgG/IgM Test Procedure

Using micropipette, add 10 µL of serum, plasma or whole blood specimen in the sample well "S"



Put 2 or 3 drops (~80 µL) of assay diluents into the sample well marked as "S"



Interpret test results in 15-20 minutes.



Do not read the results after 20 minutes.
Reading too late can give false results.

Interpretation

Negative
One pink line "C" in result window

Positive
1. IgM positive
Two pink lines "C" and "M" in result window. It is positive even if "M" line is weak.

2. IgG positive
Two pink lines "C" and "G" in result window. It is positive even if "G" line is weak.

3. IgG and IgM positive
Three pink lines "C", "M", "G" in result window. It is positive even if "G" line is weak.

Invalid
-No control (C) line in result window.
-It is recommended that the specimen be re-tested.

Interpretation of Test Results (Refer to Figure)

Interpretation of the test (Refer to figure)

Negative

The control line is only visible on the test device. No IgG and IgM antibodies were detected.

IgM Positive

The control line (C) and IgM line (M) are visible on the test device. This is positive for IgM antibodies to Syphilis

IgG Positive

The control line (C) and IgG line (G) are visible on the test device. This is positive for IgG antibodies to Syphilis.

IgG and IgM Positive

The control line (C), IgM (M) and IgG line (G) are visible on the test device. This is positive for both IgM and IgG antibodies to Syphilis.

Invalid

The control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Repeat the test using a new test device.

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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BIOGATELABS Manufactured & Quality Controlled by
Biogate Laboratories Ltd.
110-4238 Lozells Avenue, Burnaby, BC
Canada, V5A 0C4
Tel: 1-604-322-2955
Fax 1-604-322-2955
www.biogatelab.com

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.