

Syphilis Ab Rapid Test Cassette (Serum/Plasma)

INTENDED USE

Syphilis Ab Rapid Test Cassette (Serum/Plasma) is a rapid, serological, immunochromatographic assay for the qualitative detection of antibodies (IgG, IgM and IgA) to *Treponema Pallidum* (TP) in human serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with TP. Any reactive specimen with the Syphilis Ab Rapid Test Cassette must be confirmed with alternative testing method(s) and clinical findings.

INTRODUCTION

Treponema pallidum (TP) is a spirochete bacterium and the causative agent of the venereal disease syphilis.¹ Its natural course presents in three stages: primary, secondary and tertiary or late syphilis with long periods of latency or inactive disease.² Primary syphilis infection is defined by the presence of a chancre at the site of inoculation. The antibody response to the *T. pallidum* bacterium can be detected within 4 to 7 days after the chancre appears and remains detectable until the patient receives adequate treatment.³

The Syphilis Ab Rapid Test Cassette uses a combination of syphilis antigen-colloidal gold conjugate and immobilized syphilis antigen to detect *T. pallidum* antibodies (IgG, IgM and IgA) qualitatively and selectively in serum or plasma.

PRINCIPLE

The Syphilis Ab Rapid Test Cassette (Serum/Plasma) is a lateral flow chromatographic immunoassay based on the principle of the double antigen-sandwich technique. In this test, syphilis recombinant antigen is immobilized in the test line region of the strip in test device. After specimen is added to the specimen well of the device, it reacts with syphilis recombinant antigen coated particles in the test. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized syphilis antigens. If the specimen contains syphilis antibodies, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain syphilis 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 in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

PRODUCT CONTENTS

The Syphilis Ab Rapid Test Cassette (Serum/Plasma) contains syphilis recombinant antigen coated particles and syphilis recombinant antigens coated on the membrane.

MATERIALS SUPPLIED

1. Test Cassette 2. Pipette Dropper 3. Desiccant 4. Package Insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Specimen collection containers
3. Centrifuge (for plasma only)

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

WARNINGS AND PRECAUTIONS

1. For professional In Vitro diagnostic use only. Do not use after expiration date.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Humidity and temperature can adversely affect results.
8. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air conditioning.

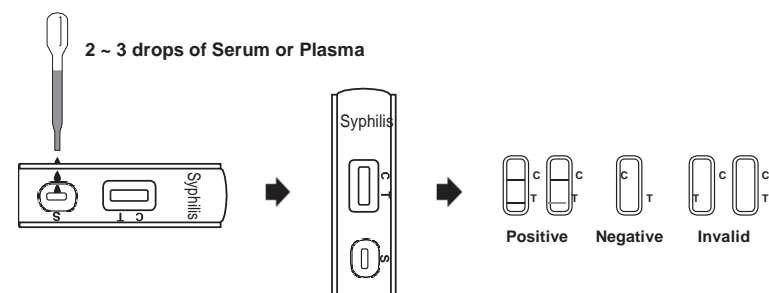
SPECIMEN COLLECTION

1. Syphilis Ab Rapid Test Cassette (Serum/Plasma) can be performed using either serum or plasma.
2. Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed specimens can be used.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
4. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
5. If specimens are to be shipped, they should be packed in compliance with usual regulations for transportation of aetiological agents.

TEST PROCEDURE

Allow test cassette, specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 2-3 full drops of serum or plasma (approx. 60-90 µl) to the sample well (S) and start the timer. Avoid air bubbles. See illustration below.
3. Wait for the red line(s) to appear. The result should be read in 15 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The Syphilis Ab Rapid Test Cassette (Serum/Plasma) is for in vitro diagnostic use only. The test should be used for the detection of TP antibodies in serum or plasma specimens only. Neither the quantitative value nor the rate of increase in TP antibodies can be determined by this qualitative test.

Syphilis Ab Rapid Test Cassette (Serum/Plasma)

2. The Syphilis Ab Rapid Test Cassette (Serum/Plasma) will only indicate the presence of TP antibodies in the specimen and should not be used as the sole criteria for the diagnosis of TP infection.
3. A negative result can occur if the quantity of the anti-Tp antibody present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
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.
5. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The Syphilis Ab Rapid Test Cassette (Serum/Plasma) has correctly identified specimens of a seroconversion panel and has been compared to a leading commercial Syphilis Ab test using clinical specimens. The results show that the relative sensitivity of the Syphilis Ab Rapid Test Cassette (Serum/Plasma) is 99.54%, and the relative specificity is 100%.

Results showed the Syphilis Ab Rapid Test Cassette (Serum/Plasma) vs. SyphilisTPPA

| Method | | SyphilisTPPA | | Total Results |
|------------------------|----------|--------------|----------|---------------|
| Syphilis Rapid Test | Results | Positive | Negative | |
| | Positive | 217 | 0 | 217 |
| | Negative | 1 | 349 | 350 |
| Total Results | | 218 | 349 | 567 |

Relative sensitivity: 99.54%

Relative specificity: 100%

Accuracy: 99.8%

REFERENCE

1. Fraser C.M. Complete genome sequence of *Treponema pallidum*, the syphilis spirochete. *Science* (1998); 281 July: 375-381.
2. Larson S.A., Krause S.J. and Whittington W.L. Diagnostic tests. P.1-26 in Larson S.A., Hunter E.F. and Kraus S.J. (ed), *A manual of tests for syphilis*. (1990) American Public Health association, Washington, D.C.
3. Johnson P.C. Testing for Syphilis. *Dermatologic Clinic* (1994); 12 Jan:9-17.