INTENDED USE
The Syphilis Rapid Test (Serum/Plasma) is a rapid immunoassay for the qualitative detection of antibodies (IgG and IgM) to Treponema Pallidum (Syphilis) in serum or plasma to aid in the diagnosis of Syphilis.

INTRODUCTION
Syphilis is a disease caused by Spirochete bacterium called Treponema pallidum (Syphilis). If untreated, the organisms move throughout the body and can cause damage to many organs, making syphilis a life-threatening disease if not treated early fully. The serological response to syphilis involves production of antibodies to a wide range of antigens, including non-specific antibodies and specific anti-Syphilis antibodies. The first detectable response to infection is the production of specific anti-treponemal IgM, which can be detected within 4 to 7 days after the chancre appears and until the end of the second week of infection; anti-treponemal IgG appears at about four weeks later. By the time syphilis disease symptoms develop, most patients have both detectable IgG and IgM.

PRINCIPLE
The Syphilis Rapid Test (Serum/Plasma) is a lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. In this test, recombinant Syphilis Recombinant antigen is immobilized in the test line region of the strip. 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 Rapid Test (Serum/Plasma) contains Syphilis Recombinant antigen coated particles and Syphilis Recombinant antigen coated on the membrane.

MATERIALS SUPPLIED

MATERIAL REQUIRED BUT NOT PROVIDED
1. Clock or Timer
2. Specimen collection containers.

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.
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.

SPECIMEN COLLECTION
The Syphilis Rapid Test (Serum/Plasma) can be performed using either serum or plasma.

1. Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed specimens can be used.
2. 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.
3. 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.
4. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of aetiological agents.

TEST PROCEDURE
Allow the test, specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test 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 on a clean and level surface. Hold the dropper vertically and transfer 2-3 full drops of serum or plasma (approx. 60-90 μl) and start the timer. Avoid air bubbles. See illustration below.
3. Wait for the coloured line(s) to appear. Read results in 15 minutes. Do not interpret the result after 15 minutes.

Syphilis Rapid Test (Cassette) (Serum/plasma)
INTERPRETATION OF RESULTS

![Image](image.png)

Positive: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

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

Invalid: Control line fails to appear.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedure.

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

2. The Syphilis Rapid Test (Serum/Plasma) will only indicate the presence of Syphilis 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 Syphilis infection.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The Syphilis Rapid Test (Serum/Plasma) has correctly identified specimens of a seroconversion panel and has been compared to a leading commercial Syphilis test using clinical specimens. The results show that the relative sensitivity of The Syphilis Rapid Test (Serum/Plasma) is greater than 99.9%, and the relative specificity is 99.7%.

REFERENCE


2. Fraser CM. Complete genome sequence of Treponema Pallidum, the Syphilis spirochete. Science (1998); 281 July: 375-381.

Index of Symbols

- Storage temperature
- In vitro diagnostic device
- Lot number
- Expiry date
- Catalogue number
- Contents
- Read instruction before use
- Manufacturer

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