SYPHILIS Ab

In Vitro **diagnostic (IVD)**

Immunochromatographic test on format card for the qualitative detection of antibodies to Treponema Pallidum in serum or plasma.

I. INTRODUCTION AND INTENDED USE

Syphilis Ab is a chromatographic immunoassay for the qualitative detection of antibodies to Treponema pallidum (TP) in serum or plasma to aid in the diagnosis of syphilis.
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 Centre 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 drugs user. One study reported 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 is defined by the presence of a chancre at the site of inoculation. The antibodies 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 Syphilis Ab utilizes a combination of a protein A coated particle and syphilis antigen to detect TP antibodies qualitatively and selectively in serum or plasma.

II. PRINCIPLE OF THE TEST

Syphilis Ab is a qualitative membrane strip based immunoassay for the detection of TP antibodies in serum or plasma. In this test procedure, recombinant syphilis antigen is immobilized in the test line region of the device. After a serum or plasma specimen is placed in the specimen well, it reacts with protein A 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. 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 controli line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

III. REAGENTS AND MATERIALS

Each kit contains:
1. Syphilis Ab card, with specimen dropper (25 devices).
2. Instruction for use (1 item)

REQUIRED MATERIALS (NOT SUPPLIED)
Specimen collection container
Centrifuge (for plasma only)
Timer

IV. SPECIAL PRECAUTIONS

- Syphilis Ab is for in vitro diagnosis only.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions agains microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- The test procedure must be followed carefully.

V. STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (4-30ºC/40-86ºF). The test device is stable through the exipration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE.

VI. SPECIMEN COLLECTION AND PREPARATION

- The Syphilis Ab can be performed using either serum or plasma.
- Separate the serum or plasma from blood as soon as possible to avoid haemolysis. Only clear, non-haemolysed specimens can be used. Remove the serum or plasma from the clot or red cells, respectively, as soon as possible to avoid haemolysis. Lipemic, icteric, or haemolysed specimens may give inconsistent test result. Specimens, of containing precipitate, should be clarified prior to testing.
- 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 4-8℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃.
- 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. If specimens are to be shipped, they should be packed in compliance with national regulations covering the transportation of etiologic agents.

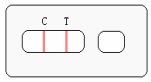
VII. TEST PROCEDURE

Allow the test device, specimen to equilibrate to room temperature (10-30ºC) prior to testing.

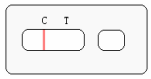
1. Remove the device from its sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 2-3 drops of serum or plasma to the specimen well (S) of the test device and start the timer.
3. Wait for the red line to appear. The result should be read at 15 minutes. **Do not interpret the results after 20 minutes.**

VIII. INTERPRETING THE RESULTS

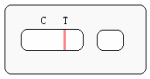
Positive: two red lines are visible in the control and test areas of the test window. **The intensity of the test line may be less than of the control line;** this still means positive result.

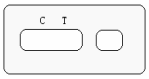


Negative: the control line appears in the window, but the test line is not visible.



Invalid: the test is invalid if the control line is not visible at five minutes. The test failed, or the test procedure was not followed properly. Verify the test procedure and repeat the test with a new testing device.





Note: the intensity of the red color in the test line region (T) will vary depending on the concentration of TP antibodies present in the specimen. Therefore, any shade of red in the test region (T) should be considered positive.

IX. INTERNAL QUALITY CONTROL

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

X. PERFORMANCES

Sensitivity

The Syphilis Ab has correctly identified specimens of a seroconversion panel and has been compared to a leading commercial TPPA syphilis test using clinical specimens. The results show that the relative sensitivity of the Syphilis Ab is 98.7%.

Specificity

The Syphilis Ab uses an antigen that is highly specific for TP antibodies in serum or plasma. The results show that the relative specificity of the Syphilis ab is 99.0%.

Precision

Within-run precision has been determined by using 15 replicates of three specimens: a negative, a low positive and high positive values were correctly identified 99%of the time.

XI. LIMITS OF THE TEST

- Syphilis Ab 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 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.
- As will all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- If the test result is negative and clinical symptom is persisting, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of TP infection.

XII. BIBLIOGRAPHY

1. Baker-Zander, S., and S. Sell. 1980. A hisethologic and immunologic study of the course of syphilis in the experimentally infected rabbit. Demonstration of long-lasting cellular immunity. Am. J. Pathol. 101:387-413
2. Baker-Zander, S. A., R.. H.Handsfield, and S. A. Lukehart. 1986. IgG and IgM antibody reactivity to antigens of Treponema Pallidum after treatment of syphilis. Sex. Transm. Dis. 13:214-220
3. Bishop, N. H., and J. N. Miller. 1976. Humoral immunity in experimental syphilis. The demonstration of resistance conferred by passive immunization. J. Immunol. 117:191-196.
4. Blanco, D. R., J. N. Miller, and P. A. Hanff. 1984. Humoral immunity in experimental syphilis: the demonstration of IgG as a treponemicidal factor in immune rabbit serum. J. Immunol. 133:2693-2697.

IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (EXXX)		Manufacturer		Keep dry	NON STERILE	Non-sterile
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

CONTENT (25 tests) **REF. VQ83000**

Syphilis Ab device with specimen dropper 25 devices
Instruction for use 1 item

EDMA Code 15 70 01 05 00 CE IVD

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