

One step Syphilis strip Test for detection of Syphilis antibody in human Serum/Plasma

For *In-Vitro Diagnostic Use only*

ORDER INFORMATION

Pack Size	REF
	Device
25 Tests	SYPS 25
50 Tests	SYPS 50

CLINICAL SIGNIFICANCE

Syphilis is sexually transmitted (venereal) disease caused by the spirochete *Treponema pallidum*. The disease can also be transmitted congenitally thereby attaining its importance in antenatal screening. After injection the host forms non-treponemal anti lipoidal antibodies (regains) to the lipoidal material released from the damaged host cells as well as treponema specific antibodies. Serological tests for non-treponemal antibodies such as VDRL, RPR and TRUST etc. are useful as screening tests. Test for treponema specific antibodies such as TPHA, FTA-ABS, rapid treponema antibody tests are gaining importance as screening as well as confirmatory tests because they detect the presence of antibodies specific to *Treponema pallidum*.

ACCUCARE® ONE STEP SYPHILIS STRIP TEST is a modified TPHA, which qualitatively detects the presence of IgM and IgG class of treponema specific antibodies of syphilis in Whole blood/Serum/Plasma specimens within 15 minutes.

PRINCIPLE

ACCUCARE® ONE STEP SYPHILIS STRIP TEST utilizes the principle of immunochromatography, a unique two-site immunoassay on a membrane. As the test conjugate forms through the membrane assembly of the test card, the recombinant *Treponema* antigen-colloidal gold conjugate forms a complex with *Treponema* specific antibodies in the sample. This complex moves further on the membrane leading to the formation of a pink to deep purple colored band at the test region which confirms a positive test result. Absence of this colored band in test region indicates a negative test result. The unreacted conjugate and the unbound complex if any along with rabbit IgG gold conjugate move further on the membrane and are subsequently immobilized by the goat anti-rabbit antibodies coated at the control region of the membrane assembly, forming a pink to deep purple coloured band. The control band serves to validate the test results.

CONTENTS

Syphilis Strip with Aluminum pouch
Instruction for Use (IFU)
Desiccant

STORAGE & STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed aluminum pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test device, if the pouch is damaged or seal is broken.

PRECAUTIONS

1. For professional *In-vitro* diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all the specimens as potentially infectious. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens and tested device.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
5. Read the Instruction for use carefully before performing the test.

LIMITATIONS

1. ACCUCARE® ONE STEP SYPHILIS STRIP TEST detects the presence of *Treponema* antibodies; thus a positive result indicates a past or present infection. Positive results should be evaluated in co-relation with the clinical condition before arriving at a final diagnosis.
2. Low levels of antibodies to *Treponema pallidum* such as those present at a very early primary stage of infection can give a negative result. But a negative result does not exclude the possibility of exposure to or infection can give a negative result. But a negative result does not exclude the possibility of exposure to or infection with *Treponema pallidum*. Resting is indicated after two weeks if clinically syphilis is still suspected.
3. In order to assess the clinical response to treatment it is advisable to use again test such as VDRL, RPR.
4. ACCUCARE® ONE STEP SYPHILIS STRIP TEST detects *Treponema* antibodies in serum/plasma; other body fluid may not give accurate results.
5. In immunocompromised patients the test results must be interpreted with caution.

SPECIMEN COLLECTION & PREPARATION

1. The ACCUCARE® ONE STEP SYPHILIS STRIP TEST can be performed using either serum or plasma.
2. Separate the serum or plasma from whole blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed 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, it should be packed in compliance with federal regulations for transportation of etiologic agents.

PROCEDURE FOR TEST DEVICE

1. Collect serum/plasma in a clean test tube (approximately 0.5-1 ml may be required). Ensure that only sufficient quantity of the specimen is collected to allow submerging the colored area on the dipstick (about 1 cm high).

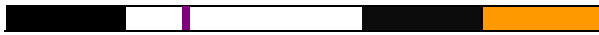
- Open the pouch, remove the dipstick and place it on a flat surface. (Once opened, the dipstick must be used immediately)
- Dip the dipstick in serum/plasma specimen submerging only the colored area.
- The dipstick should be left submerged for the entire duration of the test ensuring only the colored area is submerged in the specimen.
- Read the results at the end of 15 minutes as follows.

Specimen	Positive	Negative	Sensitivity
Positive	240	00	100 %

Specimen	Positive	Negative	Specificity
Negative	05	295	98.3 %

INTERPRETATION OF RESULTS

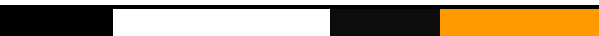
NEGATIVE: Only one pink to deep purple colored band appears on the dipstick.



POSITIVE: Two distinct pink to deep purple colored bands appear on the dipstick.



INVALID: The test should be considered invalid if neither the test band nor the control band appears. Repeat the test with a new dipstick.



Although, depending on the concentration of the treponemal antibodies in the specimen, positive results may appear as early as 2 to 3 minutes, negative results must be confirmed only at the end of 15 minutes.

INTERFERING SUBSTANCES

No interference (except HIV positive specimen) in the ACCUCARE® ONE STEP SYPHILIS STRIP TEST was evident when the following substances were tested:

Sample Type	Number of Samples Tested	Positive	Negative
Clinical Specimens	100	02	98
Pregnant women	100	01	99
Other disease Samples*	100	03	97

*Other disease Samples: These are the samples that potentially interfere with Syphilis immunoassays. Details of the samples are as follow:

Sample Type	No. of Sample Tested
HCV Positive	20
HIV Positive	20
HBsAg Positive	15
Anti-HAV Positive	15
Rubella Positive	15
Anti-HTLV Positive	15
Total	100













PERFORMANCE CHARACTERISTICS

The ACCUCARE® ONE STEP SYPHILIS STRIP TEST has been evaluated with positive and negative samples confirmed by ELISA examination.

BIBLIOGRAPHY

- Syphilis: New Diagnostic Direction, H. Young, international Journal of STD and AIDS, 1992, 3: 391-413.
- Clinical Laboratory Diagnostics: Use and Assessment of Clinical Laboratory Results, Lothar Thomas, 1st Edition, 1998, TH Books.
- AABB Technical Manual, 13th Edition, 1999.
- Clinical Diagnosis and Diagnosis and Management by laboratory methods, John Bernard Henry, 17th Edition, 1979, W.B. Saunders Company.

GLOSSARY OF SYMBOL

	Consult Instruction for Use		Lot Number
	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer		Do not reuse
	For <i>in vitro</i> Diagnostic use only		Keep Dry
	Tests per Kit		Do Not Use if Damaged