ACCUCARE
ONE STEP TEST FOR SYPHILIS

INTRODUCTION
Accucare Syphilis is a one step, rapid, self performing qualitative, two site double antigen sandwich immunoassay for the detection of syphilis in human serum or plasma specimen.

SUMMARY
Syphilis is sexually transmitted (venereal) disease caused by the spirochete Treponema pallidum. The disease can also be transmitted congenitally thereby attaining its importance in antental 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, 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 Syphilis is a modified TPHA, which qualitatively detects the presence of IgM and IgG class of treponema specific antibodies during syphilis in serum or plasma specimens within 15 minutes.

PRINCIPLE
Accucare Syphilis 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 dipstick, 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.

REAGENTS AND MATERIAL SUPPLIED
Each individual pouch contains:
1. Test dipstick: Membrane assembly predispensed with recombinant Treponema pallidum antigen-collidal gold conjugate, recombinant Treponema pallidum antigen and goat-anti rabbit antiserum coated at the respective regions.
2. Desiccant pouch.

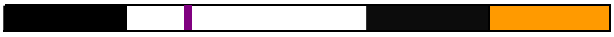
STORAGE AND STABILITY
The sealed pouches in the test kit may be stored between 4-30°C for the duration of shelf life as indicated on the pouch.

NOTE
1. For in vitro diagnostic use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimens as potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infective material.

SPECIMEN COLLECTION AND PREPARATION
No special preparation of patient is necessary prior to specimen collection by approved techniques. Through fresh serum/plasma is preferable, serum/plasma specimens may be stored at 2-8°C for upto 24 hours, in case of delay in testing. Do not use haemolysed or contaminated specimens. Turbid specimens should be centrifuged or allowed to settle and only the clear supernatant should be used for testing.

TESTING PROCEDURE AND INTERPRETATION OF RESULTS
Bring kit components, specimen to room temperature prior to testing.

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 1cm high).
2. Bring the sealed pouch to room temperature, open the pouch, remove the dipstick and place it on a flat surface. Once opened, the dipstick must be used immediately.
3. Dip the dipstick in serum/plasma specimen submerging only the colored area.
4. The dipstick should be left submerged for the entire duration of the test ensuring only the colored area is submerged in the specimen.
5. Read the results at the end of 15 minutes as follows.



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

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

6. The test should be considered invalid If neither the test band nor the control band appears. Repeat the test with a new dipstick.
7. Although, depending on the concentration of the treponemal antibodies in the specimen, positive results may appear as early as 2to3 minutes, negative results must be confirmed only at the end of 15 minutes.

PERFORMANCE CHARATERSTICS
In an in-house evaluation Accucare Syphilis was run in parallel against standard TPHA, 100% correlation was found in 103 samples.

REMARKS
1. Accucare Syphilis detect the presence of Treponemal 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 adviseable to use a reagin test such as VDRL, RPR.
4. Accucare Syphilis detects Treponemal antibodies in serum/plasma; other body fluid may not give accurate results.
5. In immunocompromised patients the test results must be interpreted with caution.

BIBLIOGRAPHY

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

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No. 3225, Chemical Zone, GIDC Sarigam,
SARIGAM - 396 155 (Dist. Valsad). INDIA
Tel : 91-22-2554 2109 / 2554 1558 ,Fax : 2554 3541
Email : accucare@labcarediagnostics.com
Website : www.labcarediagnostics.com